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CHALLENGE AND CHANGE

A Progressive Approach to Pesticide Regulation in California

Prepared for the
California Environmental Protection Agency
Department of Pesticide Regulation

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EXECUTIVE SUMMARY

By any measure, Cal-EPA's Department of Pesticide Regulation (DPR) administers the most comprehensive state-level pesticide regulatory program in the nation. The program reflects a major commitment -- and investment -- by the state's citizens. Its basic mission is to assure that all Californians have access to safe, effective, and affordable pest control systems.

The purview of DPR's responsibilities is broad, encompassing thousands of pesticide products used not only in agriculture and forestry but also in the home, on public lands, and in innumerable other settings. Pesticides prevent crop and property damage, slow spoilage, combat the spread of disease, and help people, pets, and other animals live more comfortably in a world full of sometimes unwelcome company such as mosquitos, fleas, and rats -- and, for those who suffer allergies, ragweed.

The *Base Program:* DPR has six branches: Pesticide Registration, Medical Toxicology, Worker Health and Safety, Environmental Monitoring, Pesticide Enforcement, and Information Services. It has about 345 staff members and a budget of about $41 million. In the mid-1970s, DPR had a staff of about 100. A decade ago, DPR's staff included only one toxicologist; now there are nearly three dozen. DPR's program is several times larger than the pesticide regulatory program in any other state and is slightly less than one-half the scale of base programs in the U.S. Environmental Protection Agency (EPA).

Nearly half of the applications submitted to DPR each year are found deficient in some respect, delaying reviews and approvals, wasting DPR staff time, and frustrating registrants. About 9,000 registrations are approved or renewed by DPR annually. The majority -- some 7,500 renewals -- require no new data or scientific review. Most move through the system in a matter of days as renewals, provided they are accompanied by the correct fee. About 1,000 nonsubstantive label changes annually move through the system, requiring only a few weeks each. And every year, about 1,500 new product registrations are granted and about 1,500 existing registrations are dropped.

Most of DPR's scientific effort is invested in 2,000-2,400 actions annually that involve new products or substantive label amendments. Many of these actions are delayed while data gaps or other problems with applications are corrected. Once studies are found complete and ready for review, they move into DPR's system but generally encounter slow going somewhere along the way.

Certain review stations face chronic backlogs, especially the Medical Toxicology Branch. On average in 1991, it took 132.8 days for a package to move through DPR's entire evaluation process -- 120 days sitting on desks caught up in backlogs and just under 13 days being reviewed by the various relevant stations. When initial reviews suggest the need for an in-depth risk assessment, several more months or even a few years may be needed to collect and analyze additional data.

DPR's risk assessment conclusions and regulatory actions often trigger controversy. Registrants typically contend DPR is too cautious and overstates risk; environmentalists counter that DPR doesn't follow the law and is too willing to bend the rules and science to get or keep pesticides on the market. But DPR's decision making is much more solid than its critics contend, especially when evaluated in light of the legislative mandates and administrative regulations DPR is charged with implementing.

Just since 1990, DPR has handled about 40,000 submissions of data, registration applications, requests for state registrations, and other sorts of actions. As dictated by new state laws, the volume of data needed to receive or retain most types of registrations has more than doubled in the last decade, with more requirements looming on the horizon -- especially data needed to more accurately characterize immunological and neurotoxic risks and risks to infants, the elderly, the ill, and other uniquely exposed or at-risk segments of California's diverse population.

In addition to the routine flow of work and its attendant controversy, DPR is almost always responding to some significant exogenous shock. For example: a major, ongoing pesticide storage facility fire; an unexpected new study that erodes overnight a pesticide's previously comfortable margin of safety; legislative actions establishing new responsibilities while providing no new resources; or, a major spill like the tanker car that plunged into the headwaters of the Sacramento River near Dunsmuir on July 14,1991 -- ironically, three days before Cal-EPA came into existence.

DPR's NEW MISSION -- AND DILEMMA

On January 29, 1991, Governor Pete Wilson announced plans to establish a state-level environmental protection agency, Cal-EPA, which would include among its major programs the California Department of Food and Agriculture's pesticide regulatory program. In July 1991, when the reorganization plan took effect, Cal-EPA and DPR were charged with the following mission:

- Give the most urgent attention to the greatest risks
- Set risk-based priorities based on rigorous and internally consistent science
- Prevent pollution
- Balance environmental protection and economic growth

- Vigorously and consistently enforce laws enacted to protect environmental quality

- In regulatory decision making, seek consensus with and support from all levels of government, as well as industry, agriculture, environmental groups, and concerned citizens

Dilemma DPR is forceful and generally effective in carrying out its responsibilities as established by law. But the path defined by current policy may sometimes reduce the effectiveness of pest control efforts and increase agricultural production costs. In addition, further shrinkage of the pesticide tool kit may increase the adverse environmental and public health consequences of crop protection practices in some regions and crops by the mid-to-late 1990s. That is DPR's dilemma: federal and state policies threaten to create the problems DPR is dedicated to avoiding.

Californians and indeed the nation's consumers have developed a taste for the fruits and vegetables, wines, and specialty crops grown in the Golden State. The challenge facing DPR in the 1990s is to find better ways to use its pesticide regulatory tools and authorities to advance public safety and enhance environmental quality without undermining the economic viability of the state's $15 billion agricultural industry. At stake are affordable access to a nutritious diet, millions of jobs, and the economic base of many communities.

The Existing Path Since the mid-196Os, the path chosen by regulators to balance the needs of agriculture and the environment has had two channels: first is to identify hazardous pesticides and try to get them off the market while, secondly, to rigorously test all new products to make sure newly registered pesticides will be safe if they are widely used. This path is now cast in concrete by a dozen major federal and state laws, and the country is moving briskly -- indeed, some would *argue blindly* -- along it.

Steps taken by the federal EPA and DPR to administer these laws have reduced the number of federally registered pesticide active ingredients from 1,153 in 1989 to 678 in 1992: a drop of over 40 percent. (An "active ingredient" is the chemical in a formulated pesticide product most responsible for the product's ability to control target pests). The total number of registered pesticide products containing these active ingredients declined from 45,000 to 19,200 between 1989 and 1992. For many high value fruit and vegetable crops, the number of products available is now perilously small.

Farmers aren't the only ones wondering what's next in the war against pests. People needing to fumigate homes for termites or wood-chewing beetles have no pleasant choices either, whether in terms of cost or risks. A few effective and promising new products are registered each year, but a much larger and growing number of old pesticides are not working as well as they once did.

The switch to safer systems of pest control is hampered in many crops and situations by the lack of proven and affordable nonchemical control alternatives. This problem confronts all growers -- conventional, organic, part-time, and back yard. The agricultural community is testy about pressure from environmentalists to change rapidly, in part because California agriculture is stressed on several fronts at once: the shift of production to Mexico, growing competition for markets, higher costs for water and labor, and conflicts with urban and suburban communities increasingly unwilling to put up with the sights, sounds, smells, and hazards of farming.

CHANGE

The likely near-term pesticide policy scenario is that many more products will be pushed off the market, and getting new products onto the market will remain costly and difficult. Only large, established companies with profitable product lines will be able to afford the research and development (R+D) and regulatory compliance costs to get approval from EPA and DPR for new products. Small companies -- including those applying the tools of genetic engineering to plant protection and those trying to get natural compounds registered -- will only rarely be able to afford the price of admission.

Without changes in regulatory and research policy and direction, the pest control tools available will continue to diminish. Until effective alternatives are discovered and proven, growers will lose options and some will rely too heavily on the ones that remain. This is a recipe for trouble.

Impatience While farming practices are changing in California, change is slow and requires patience because farmers have no choice but to work within annual cycles as they learn new ways to cooperate with nature. Despite the fact that California is unambiguously ahead of the rest of the nation in moving sustainable agriculture practices into mainstream farming systems, many citizens and most environmental activists in the state believe that pesticide policy is perpetuating ineffective and unacceptably hazardous methods of pest control. They are impatient with the rate at which California is dealing with pesticide hazards and convinced that the state's farmers will quickly discover economically viable pest control alternatives if only regulators would pull the pesticide plug. Toward this end, activists have been pushing on every front -- in DPR and EPA administrative processes, in the state Legislature and U.S. Congress, in the courts, and with the media and general public.

Arguments from the environmental community work well in the policy arena in no small part because the evidence supports their case that many conventional pesticide-based control systems are getting harder to justify, sometimes pose high risks, and can be significantly improved by adopting a more sophisticated, biologically-based approach to pest control. Yet those who believe fewer pesticides will mean safer pest control may be disappointed if DPR sticks to its current path.

"SAFE" AND "SAFER"

Several generally unfamiliar terms are used throughout the report. Definitions for them follow. We believe these definitions are among the most important recommendations offered in this report, because they will give both state and federal regulators new tools to help set and act on priorities *and* to decide when certain regulatory actions should be expedited.

Safe pesticide product is an absolute term -- "absolute," in this case, meaning compared to a distinct standard, rather than in the sense of forevermore certainty. It refers to a pesticide product with desirable physical, chemical, toxicological, biological, *and* ecological properties that render it capable of accomplishing its intended impact on target pest species while having insignificant or no adverse impact on humans, the environment, or the ecology of plant-pest interactions ("insignificant or no" means an exceptionally low probability of negative impacts: a finding that regulators would make based on available product and field use data). If "safe pesticide products" were defined only by absolutes -- zero risk, no chance of posing risk -- then few if any products would fit within the definition.

Safer pesticide product is a relative term. It is used to denote a pesticide product with one or more desirable physical, chemical, toxicological, biological, or ecological properties relative to other registered pesticide products or nonchemical pest control alternatives.

Safer pest control *system* is a relative term that encompasses most integrated pest management and biocontrol systems, which -- relative to pesticide-intensive control systems -- successfully incorporate use of plant genetic, cultural, and biological control methods as a first line of defense.

DPR has shown that regulation can play both a catalytic and constructive role in shaping safer systems of pest control, even without new regulatory tools. California's approach to addressing rice herbicide problems is an impressive example. By changing the system within which rice herbicides were used, farmers reduced the mass transport of one common herbicide in the Sacramento River from 40,667 pounds in 1982 to 220 pounds in 1991: a reduction of 99.5 percent -- with no appreciable change in the cost or quality of weed control.

The rice herbicide program demonstrates the value of finding improved ways to manage pesticides *within the farming systems in which they are used.* It confirms that DPR can design and that the county agricultural commissioners can enforce pest management systems that dramatically reduce risks and environmental damage while also allowing growers to retain access to pesticides that work well and are affordable. There is every reason to believe that this model, or at least its essential elements, can be constructively applied in other crops and regions as DPR strives to promote safer systems of pest control. The report offers specific recommendations for how DPR and the agricultural community could test this assertion.

CONCLUSIONS

DPR commissioned this study as an independent assessment of its current programs and activities. We found that DPR is a proficient regulatory agency; nevertheless, many policy and procedural changes are needed to accelerate progress toward safer pest control systems. Without change, pests will begin gaining the upper hand and even more challenging public health and environmental risks and more costly regulatory efforts will become inevitable. Despite controversy, resource limitations, and volatile episodes, DPR has had some encouraging victories:

- Significant progress has been made in filling long-standing data gaps for the 200 most widely used pesticides: over 80 percent of all required core toxicology studies are now completed or underway -- up from 53 percent in 1988

- Just weeks after a new study pointed to unacceptably high risks from the use of methyl bromide as a structural fumigant, significant new safety precautions were put in place statewide through emergency regulations -- safety precautions the EPA has now required nationwide

- Systematic efforts in compiling field level exposure data and refining worker safety risk assessment methods have set the stage for steady progress in reducing the frequency and severity of poisoning incidents

DPR deserves national recognition for its contributions of new methods to characterize, quantify, and reduce pesticide risks faced by applicators and farmworkers. Worker exposure problems remain in California, but no other state program -- nor EPA -- is as well-prepared as DPR to manage those risks or as committed to doing so.

BUILDING ON STRENGTHS

The recommendations in this report are designed to build on DPR's existing strengths and to articulate new policies DPR needs to implement to help the pesticide registration program contribute to achievement of Cal-EPA's overall goals. Implementation will require, in some cases, new resources or changes in law, or both.

Recommendation: Cut by at least one-half over the next two years the average time span required between EPA approval and use in California for new active ingredients and new products

Recommendation: Amend the Permit Reform Act and/or modify its implementing regulations

Recommendation: Overcome gridlock and delays by periodically purging the system of backlogs

- Manage reviews so that much less time is lost to backlogs

- Declare a moratorium twice a year when no new applications will be accepted

- Alter the fee structure to create incentives for careful attention to detail and completeness when applications are first submitted

Recommendation: Foster easy communication and timely understanding of changes in policy

- Establish an "Ombudsman Office" and procedures for clear and efficient communication with registrants on pending applications

- Provide training sessions and materials for the regulated community

- Make changes in registration policy and procedure in an annual cycle

SETTING PRIORITIES

DPR lacks adequate mechanisms to focus its efforts on high risk pesticides and high risk use patterns. Because DPR's workload will increase and its resource base will likely decline, effective priority-setting will be increasingly essential.

Recommendation: Enhance DPR's authority to take regulatory action swiftly -- specifically, DPR should:

- Be given the authority and political support to say no sooner and yes faster

- Rely upon experience and prudent judgement more frequently and earlier in the review process

- Work cooperatively with EPA, avoiding duplication of effort and developing specialized expertise tailored to augment EPA's

- Seek public input in resolving long-standing pesticide policy disputes and, in the meantime, explain clearly the criteria and decision rules for taking action

Recommendation: Keep the process open and the rules explicit

- Hold public workshops and invite guidance on key regulatory program decision rules

- Publish interim guidelines for pesticide regulatory decision making

- Customize policies and procedures to apply data requests systematically and to uniformly achieve risk mitigation targets

Recommendation: Go after bad actors

- Focus data requests strategically on high priority concerns
- Develop methods to screen new data packages for surprises and target scientific review resources
- Systematically focus scientific staff on efforts designed to reduce risks from high priority pesticides registered for use within high risk use patterns
- Institutionalize assessment of high risk use pattern pest control options -- past, present, and future
- Over two years, expand margins of safety within high risk pesticide use patterns to acceptable levels

Recommendation: Change or waive efficacy data requirements so that useful information is produced and so that entry to the California market is not delayed

THE STATE AND FEDERAL PARTNERSHIP

A new foundation must be established in law and practice for the state-federal partnership in pesticide regulation to have practical meaning in California. Working together, both DPR and EPA can be made wiser in the face of scientific uncertainty and stronger in the face of criticism. As things stand now, however, the federal reregistration process has the two programs moving at a brisk pace on a collision course. Only decisive leadership and changes in federal law can prevent frequent and possibly bitter confrontations over specific policies and actions.

To fully capitalize on EPA's and the pesticide industry's enormous investment in reregistration, states must be given a much more meaningful opportunity to craft risk reduction measures needed to address exposure and risk scenarios unique in a particular state, or in regions of a state. If federal reregistration decisions fail to rise above the lowest common denominator, aggressive state regulatory agencies -- and DPR is not the only one -- will find ways to work their will.

Recommendation: DPR and EPA should cooperate to the fullest extent possible to:

- Coordinate design and enforcement of risk mitigation measures
- Develop areas of specialized expertise and responsibility to augment each other's strengths and capabilities
- Support utilization of DPR's specialized expertise applicable to national problems

Recommendation: EPA and the Congress should give states a meaningful role in decision making on risk reduction and label amendments -- for example:

- DPR and EPA should share the risk assessment load to speed progress and tailor risk mitigation measures to unique state needs

- States should be authorized to add supplemental state-specific labelling alongside federally approved pesticide product labels

- DPR should blend California-specific data requirements to the fullest extent possible with data requirements imposed by EPA

TOWARD SAFER SYSTEMS OF PEST CONTROL

Regulating *products*, rather than the safe use of products in the context of a biointensive integrated pest management *system* is obsolete. Using state-of-the-art methods of risk assessment and risk mitigation, regulation should derive from a systems-based appraisal of ways to reduce risks by expanding control options within particular pest-crop combinations. Regulation to advance safer systems of pest control must have at least these four components:

- Timely registration of safer products

- Restricted application of ecologically disruptive products

- Increased use of alternatives to conventional pesticides

- Experimental efforts to design and license pest control systems

Incremental implementation of this approach would mean that DPR could act swiftly to impose risk mitigation measures and request field monitoring data to use in calibrating risk reduction goals according to actual field experiences. Incremental implementation also would allow for such innovations as fast track approval on an *interim* basis of any proposed label amendment that includes a 30 percent or more reduction in risk and "provisional registration" for safer pesticides.

The effectiveness and affordability of safer systems of pest control depend on access to a diverse array of tactics and tools such as chemical, genetic (for example, pest resistant plant varieties), cultural, and biological control products and technologies. Furthermore, the most important resources in the implementation of biointensive pest management systems are real-time information on *actual* pest-crop interactions in given fields, coupled with the knowledge, experience, and skill required to translate that information into effective biologically-based control systems.

Recommendation: Administer pilot projects to test the feasibility of crop protection system licensure

- ACADEMIC: Integrate IPM system practices called for by the University of California into pesticide product labels and permit requirements

- *EXPERT SYSTEM/PRESCRIPTION USE:* Prescription use within biologically-based IPM systems designed and implemented jointly by growers and agricultural consultants

- *JOINT POWERS AUTHORITY (JPA):* Establish a joint powers authority to license DPR-approved pest control systems and help growers to implement them

Recommendation: Establish a cooperative agreement with the University of California, Riverside to monitor pesticide resistance in the state's major pest species

Recommendation: Modify the "no alternatives" rule, on which DPR now bases denial of certain applications, to acknowledge cases in which an additional product will reduce risks and promote sustainable crop protection systems

Recommendation: Reassess soil fumigation products and practices -- the state's single most worrisome example of a high risk use pattern -- and encourage adoption of safer alternatives

Recommendation: Progressively refine exposure assessments and risk mitigation measures through field monitoring and enforcement activities

CHAPTER I: INTRODUCTION

On April 17,1991, Governor Pete Wilson issued his Governor's Reorganization Plan No. 1 (GRP- l), announcing his intention to establish a state-level environmental protection agency: Cal-EPA. A key institutional change in the reorganization to create Cal-EPA was to move authority for pesticide regulation from the California Department of Food and Agriculture (CDFA) to a new department within Cal-EPA: the Department of Pesticide Regulation (DPR). Prior to the reorganization, DPR had been CDFA's Division of Pest Management, Environmental Protection, and Worker Safety.

The Little Hoover Commission held hearings on the Governor's proposed reorganization plan on May 22 and 23, 1991. Testimony addressed a range of issues, including the consequences of moving CDFA's Division of Pest Management into Cal-EPA (see California Farm Bureau Federation statement), how risk assessment versus risk management functions would be carried out within Cal-EPA (see California Association of Professional Scientists and Natural Resources Defense Council statements), and ways to pursue the pollution prevention and technology-forcing elements within Cal-EPA's goal statement (see Benbrook testimony). A white paper presented on behalf of the Western Agricultural Chemicals Association summed up industry's generally positive view of the reorganization plan:

> Over the years, California has made significant investment in its pesticide regulatory and enforcement program. As a result, California has the most sophisticated, well-financed and most aggressively enforced pesticide management program in the nation, if not the world. It is a system based on scientific determination by knowledgeable staff possessing [the needed] expertise....

In July 1991, the reorganization plan took effect as proposed, and Cal-EPA became a new agency of California state government charged with the following mission (see GRP-1):

- Give the most urgent attention to processes and substances presenting the greatest risk to public health and the environment
- Set risk-based priorities based on rigorous and internally consistent science
- Prevent pollution
- Engage the private sector in environmental protection through the mechanism of market incentives
- Vigorously and consistently enforce laws enacted to protect environmental quality

- In regulatory decision making, seek consensus with and support from the national government, other parts of state and local government, the Legislature, industry, agriculture, environmental groups, and concerned citizens

The "Ueberroth Report" In December 1991, the Governor convened a 17-member Council on California Competitiveness, chaired by Peter Ueberroth, to make recommendations designed to address the gap between state revenues and the needs of state government. In April 1992, the Council issued its report, *California's Jobs and Future, in* which it stressed the "need for a new attitude about the relationship between our environment and our economy."[1]

Over the course of its study, the Council held hearings at which government as well as business representatives had characterized their experiences with environmental regulation as "burdensome" and "excessive." Analysts working with the Council concluded that testimony and other evidence prepared for the Council's consideration indicated that the proliferation of regulatory agencies has become unmanageable and that this condition lends itself to two types of mischief. First, regulatory agencies tend to be single-purpose and, as a result, they focus on solving one particular problem without having to account to anyone for the *general* socioeconomic impact of the actions they take or require others to take. Second, they tend to be funded by fees and fines, often escaping the same degree of scrutiny applied to government functions funded with general tax revenue -- and, in the Council's words, "foster[ing] an attitude of arrogance."[2]

The formation of Cal-EPA is clearly compatible with the Council's overall preference for what it refers to as "regulatory streamlining." It is too early, however, to predict whether the Council's recommendations will be fully implemented. If, for example, the Governor and Legislature were to agree with the Council that "all appropriate fees and fines collected from the regulated community [should] be deposited into the general fund"[3] -- including, perhaps, revenue from the pesticide mill tax -- the ability of DPR to sustain the comprehensiveness of its current pesticide regulatory program would be in doubt.

Historical Evolution of Pesticide Regulation By any measure, DPR administers the most comprehensive state-level pesticide regulatory program in the nation. California has regulated pesticide use for 81 years -- just one year short of the federal government's effort. Historically, DPR's goal has been to assure that each pesticide registered for use in the state is effective and can and will be used not just safely but with a *margin* of safety that is ample -- provided the use

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[1]Council on California Competitiveness, *California's Jobs and Future* (Sacramento, CA: 23 April 1992), 31.

[2]*Ibid., 28.*

[3]*Ibid., 32.*

restrictions, safety precautions, and risk mitigation measures prescribed on the label are either voluntarily adhered to or enforced.

DPR's pesticide regulatory responsibilities initially focused on products used to control pests affecting agricultural producers. Early pesticide laws at both the state and federal level were passed in the 1910s out of concern that "snake oil" salesmen were offering farmers sometimes dangerous potions of no real value for crop protection. So from the beginning, demonstrating the *efficacy* of pesticide products has been a cornerstone of pesticide regulatory law.

Over the years, the variety of pesticide products, the ways and places they are used, and their intended targets have expanded. As a result, the purview of pesticide regulators has expanded far beyond the farm, encompassing a vast array of products used to protect the home from termites and other wood-chewing pests; disinfectants and sanitizers used in schools, restaurants, and hospitals; products used to control public nuisance pests such as mosquitos, ants, fleas, and ticks (some of which can be vectors for human disease); specialty products for use on pets, in storage facilities, and to preserve all sorts of products manufactured out of wood, cotton, wool, or other materials subject to attack by pests.

Since the 196Os, the volume of *herbicides* (pesticides applied to control weeds) has grown steadily. In the 195Os, herbicides made up only a small fraction of the total pounds applied but, in the 199Os, herbicides are by far the dominant class of pesticides used nationwide (although not in California). The pounds of *insecticide* used, on the other hand, have dropped off and new classes of pesticides -- more specific in their mode of action and some developed and/or manufactured through genetic engineering techniques -- are beginning to gain a foothold in the marketplace.

Few people are aware that the need to treat water for bacteria and to control algae growth leads to more pounds of pesticide use in California than any other need. Statewide in 1990, out of a total volume of just over 605 million pounds of pesticides, 227 million pounds -- or 37.5 percent -- were chlorine, most of which was used by municipal water treatment facilities and in the food processing industry. Thus a single active ingredient, chlorine, accounts for more than one in every three pounds of pesticides used in the state. To place this volume in perspective, insecticides comprise the class of pesticides that is most often in the news in California. In 1990, about 49 million pounds of insecticides were used statewide: one pound of insecticide for every 4.6 pounds of chlorine.

Growing public concern in the 1960s over the ecological and human health risks associated with the use of DDT and other chlorinated hydrocarbon insecticides set in motion the second major wave of changes some 50 years after concern for product efficacy had dominated the focus of regulators. Just as the diversity of pesticides and the range of their use expanded, so too did the range of questions the public started to raise about the wisdom of widespread release of toxic compounds into the environment and in and around homes, parks, and other public facilities.

Public concerns spurred political action. A steady stream of new state and federal laws has been passed, calling upon regulators to request and evaluate pesticide risks more comprehensively. While pesticide regulation in California has never been quiescent, the pace of change has accelerated appreciably since the mid- 1970s when the precursor to DPR's program operated with a staff of about 100 person years. The figure grew to 266 person years in 1985-86 and, in 1992, DPR's staff level is now just over 345 person years -- an increase of 245 percent since the mid-1970s. Despite significant staff growth, the workload facing DPR, if it is to implement the laws which *already* have been passed, has grown even faster and will not peak for perhaps another 10 years.

CONTEXT FOR PESTICIDE REGULATION IN THE 1990s

For those involved with it, pesticide regulation is often the proverbial "hot potato" among California's regulatory functions. Nearly all of DPR's major decisions are met with criticism, sometimes from all sides. New problems become apparent as fast as old ones are solved. Each new set of problems tends to be more difficult to solve as the range of alternatives narrows and the interactions of farming practices, pest control technology, ecology, and regulation become more volatile. For the program's detractors, disaster continuously looms around the corner, either because of DPR's actions or its inaction. Nothing in the current environment suggests that these volatilities of pesticide regulation are about to subside.

SUGGESTED PESTICIDE REGULATORY POLICY GOALS FOR CALIFORNIA IN THE 1990s

For farmers, land managers, pest control advisors and operators, and homeowners, the goal is to ensure timely access to pest control products, techniques, and systems that work safely and effectively in the wide variety of climatic, soil, and target-site conditions found across the state and are affordable.

For *all* Californians, the goals are to ensure access to a wide variety of high quality foodstuffs and to provide protection from pests that transmit diseases, cause food spoilage, degrade water quality, or inflict damage on property.

Over the past 15 years, regulators have been compelled by human health and environmental quality protection mandates enacted during the 1970s to impose pesticide use restrictions or even to suspend registrations. Since the mid-1980s, when the California Legislature passed the first of that decade's major pesticide bills (SB 950, The Birth Defect Prevention Act of 1984), registrants have decided with increasing frequency to voluntarily withdraw certain products, citing the cost of regulatory compliance, lack of markets, inherent toxicity, or other factors.

Quite apart from the impact of regulation in narrowing the pesticide tool kit, growers may rely too heavily on one or a few pesticides simply because they work really well, there are few registered alternatives, or because they are cheaper to apply. Whatever the reason, when growers -- or homeowners -- adopt unilateral control programs, pest biotypes that are resistant to pesticides

sometimes emerge, or new (or "secondary") pest problems evolve that become more difficult to deal with than the original target pest.

Unfortunately, we keep relearning a costly lesson: that restricting the *number* of pesticides available for use on a given crop, or against a target pest in a non-agricultural setting -- either by regulation or through market forces -- does not necessarily reduce the *risks* associated with pesticide use, or even the volume applied. This paradoxical outcome is most likely to become reality when pesticide users find themselves with just one or two products left to use in their efforts to control a particular pest. In this sense, regulators may win a specific pesticide risk reduction battle only to set the stage for losing the generic pest control war.

Working Biology Back into the Agricultural Equation Driven by economic realities, declining pesticide efficacy, and environmental concerns, California agriculture is moving toward the end of *the predominantly* chemical era of crop protection and is moving into an era characterized by information-intensive biorational pest management systems.[4] Both natural and synthetic pesticides and biocontrol agents will remain vital components of such systems. But the big difference will be that chemicals, especially broad spectrum products, will no longer automatically be the first and dominant line of defense.

This transition is well underway in a few crops and regions. However, for many crops and pests, especially several low-acreage but high value minor use crops, tangible progress will take a decade or perhaps much longer and will happen at all *only* if essential scientific advances are made. For such advances to occur, both public and private sector research and development (R+D) priorities will need to change in the years ahead. This process is well-underway in at least some companies and research institutions.

Already, innovative growers and their advisors are discovering ways to reduce certain types of pest pressure, often markedly, thereby lessening reliance on conventional chemical pesticides. In the case of insects, they accomplish this by managing the ecological niches available to pests and by using new biocontrol products and techniques to disrupt normal pest behavior. The goal is less often to *kill* the insect than to *manage* its population level. Tactics include disrupting successful mating, blocking normal physiological development, or discouraging normal feeding and flight patterns.

4"Biorational" means environmentally benign, or "friendly." (See page 37 for definitions of key terms used throughout this report. Also, see the glossary for additional definitions.) The use of even highly toxic pesticides can be biorational if such products are (1) specialized in the sense that they destroy only a particular target organism and have little or no impact on beneficial insects, field workers, or environmental quality; and (2) applied only as prescribed within the context of a *system* of pest control designed to correct documented pest problems in a given field that is being monitored by trained scouts.

In the case of plant diseases and weed control, other practices and tactics are used to lessen the need for conventional pesticides. The most prevalent and successful are the breeding of genetically resistant plant varieties and root stock, along with careful attention to sanitation (that is, assuring that infected plants or soil are not brought onto a farm). Weed control is achieved in different settings in a wide variety of ways, including hand weeding, use of plastic mulches, mowing, and mechanical cultivation.

Cutting back on the volume of broad-spectrum pesticides applied will make it easier to build populations of beneficial species and microorganisms, both above and below the ground. Greater species diversity will generally lead to more stable plant-pest interactions, while also helping farmers efficiently recycle crop wastes, manure, and other sources of organic matter into humus and available plant nutrients.

Skilled pest management practitioners will often be able to channel enhanced complexity in plant-pest-nontarget species interactions into a greater array of pest management tools and tactics. These changes on the farm, in turn, will challenge lawmakers and regulators to rethink the basic goals, criteria, and decision rules governing pesticide regulation, research goals and priorities, and enforcement policies.

Perspectives of Interest Groups Different constituencies use different yardsticks in measuring DPR's performance. Some assign priority to agricultural production; others emphasize public health and environmental quality first and assume that the agricultural community will find ways to adapt to more restrictive regulation. Others focus narrowly on how regulation affects a very specific need -- such as fumigants to preserve dried fruits shipped from California to the Far East.

Legislators and regulators face the difficult task of striking a balance among conflicting goals and expectations -- a task made even more difficult by the number and breadth of well-organized and well-financed special interests. Each interest group tends to evaluate DPR's performance relative to the degree to which DPR's policies and actions support its own needs and goals.

Growers: From the perspective of growers and land managers, key pest control and regulatory goals include:

- Economically acceptable crop, plant, and livestock production losses to pests
- Reliable year-to-year pest control
- Affordable pest control relative to other growers of the same crop in other regions
- Straightforward pesticide label directions and safety precautions which can be implemented without excessive cost, time demands, or burdensome safety gear

Farmworkers and Environmentalists: From the perspective of farmworkers and those concerned about environmental quality in and around areas treated regularly with pesticides -- including growers who are pioneering innovative crop protection systems out of their concern for the environment -- key pest control and regulatory goals include:

- Steady progress in reducing the frequency and seriousness of pesticide poisoning incidents and illnesses among field workers, pesticide applicators, and structural pest control experts

- Reduced volume of pesticides applied, especially pesticides of greatest concern because of their toxicity and/or environmental effects

- Ample margins of safety must be assured for workers, wildlife, and the environment

- Lessened reliance on pesticides that leave residues on or in food near and sometimes above levels of concern -- either for consumers (through the diet) or for field or food processing workers

- Changes in pesticide use patterns to reduce residues in soil, air, and water below damage threshold levels for non-target organisms, wildlife, or humans

Industries Serving Agriculture: From the perspective of pesticide manufacturers, registrants, retailers, applicators, and pest control advisors, key pest control and regulatory goals include:

- Timely regulatory decisions

- Application of accepted science-based criteriain accordance with specified standards

- Equitable and evenly spread costs and consequences of regulation

- Innovation and common sense in policy setting and crafting of risk mitigation measures

- Preservation of options for professional pest control specialists to exercise judgement in using products, technology, and real-time information to manage pests optimally

AUTHORITY AND STATUS

In the years ahead, DPR's risk assessment procedures and risk management policies will be assessed and debated relative to those in other programs within Cal-EPA. Pressures on DPR to regulate more aggressively could grow as progress is made in other areas of environmental

protection. Already, monitoring activities carried out as part of the state's clean air and water resources programs have forced changes in DPR policies and priorities.

For well over a decade DPR's risk assessment methods, policies, and decisions have been compared to and contrasted with EPA's. This is sure to continue, helping to sharpen the contours of one of the key pesticide policy issues in the 1990s: the division of pesticide regulatory authorities and activities between the state and federal levels of government. Moreover, DPR is likely to step out in front of EPA with increasing frequency by requiring additional applicator and worker safety risk mitigation measures on a routine basis.

Whether shaping its policies and actions within Cal-EPA or seeking common ground with federal EPA, DPR will have to continue to prove that its actions are science-based, justified, and effective in reducing risks, while also assuring pests are kept in check without undue economic hardships. It will need to function confidently at the cutting edge of science and convincingly articulate the basis of and reasoning for its actions, or inaction. DPR must meet these challenges continuously or risk eroding its base of political support -- an outcome to be avoided, given intense pressures to cut the cost of state government.

DPR should periodically review its policies and priorities and act upon opportunities to improve the efficiency of its programs -- even when such changes are not universally popular. As it has done in the past, it should respond substantively to its critics and should act decisively to implement constructive recommendations. Still, because so many new challenges are on the horizon, DPR needs to become more decisive in overcoming program weaknesses and constraints -- both those it identifies through internal reviews as well as those highlighted by outside critics.

Responding to Its Critics While still functioning as the Division of Pest Management within CDFA, DPR was periodically the subject of critical reports issued by the Senate and Assembly Offices of Research. The seminal reports were:

- *Pesticides and Regulation: The Myth of Safety,* California Senate Office of Research, April 1991 (hereafter referred to as *Myth of Safety* report)

- *Regulation vs. Practice, A Review of the California Department of Food and Agriculture's Pesticide Registration Process,* Senate Office of Research, February 12, 1990 (hereafter referred to as the SOR report)

- *The Invisible Diet: Gaps in California's Pesticide Residue Detection Program,* Assembly Office of Research, April 1988 (hereafter referred to as *Invisible Diet)*

- *Pesticides at Home: Uncertain Risks and Inadequate Regulations,* Senate Office of Research, April 1988

These reports received considerable media coverage and helped fuel ongoing pesticide policy debates. They cover a wide range of topics and offer dozens of recommendations, many of which have been implemented. The *Myth of Safety* report focused on risks from indoor uses of pesticides, particularly neurotoxicity and other risks faced by children. These risks had received little attention in past pesticide regulatory policy debates. The report offered several recommendations calling for better exposure and toxicity data and greater attention to non-agricultural use patterns.

Invisible Diet was based on and largely repeated recommendations offered in a 1985 Little Hoover Commission report, *Control of Pesticide Residues in Food Products: A Review of the California Program **of** Pesticide Regulation* (Commission on California State Government Organization and Economy [Little Hoover Commission], March 1985). The 1985 and 1988 reports made the case for markedly expanding CDFA's residue testing program, and offered recommendations which led to the current structure of California's food residue monitoring program.

DPR's Response to the SOR Report Pesticide regulation periodically becomes a highly volatile issue in California, as it did in the 1989-91 period in the wake of the Alar episode and high-visibility efforts associated with the "Big Green" ballot initiative in 1990. Under intense scrutiny during such periods, DPR has been known to overreact to its critics. Occasionally, DPR's critics or constituencies have unwisely advocated policy changes -- either administrative or legislative -- which proved to be poorly conceived or otherwise detrimental in the context of DPR's overall mission and long term goals.

For example, the 1990 Senate Office of Research report focused on several instances in which DPR decision makers appeared to disregard or overrule staff scientists who had raised concerns or questions about the hazards associated with particular pesticide products. The report offered a number of recommendations to strengthen the autonomy of scientific reviewers within the program and to discourage, if not prohibit, the granting of registrations until all such concerns or questions are resolved.

The SOR report had significant impact on DPR. The decision process undeniably slowed. It pushed the authority to stop a registration action downward in the organization and made senior managers more reluctant to grant registrations until *all* required data were in-hand and *all* risk-related concerns satisfactorily resolved. Scientific staff gained greater authority in deciding whether ongoing uncertainty about the risks posed by a pesticide was worrisome enough to hold up a registration action. Program-wide, heightened importance was vested in compliance with process and procedure. Several pesticide products used widely for years which had been exempt from the process became subject to thorough reviews. Many individual staff in the program became less willing to accept conjectural or poorly documented claims by registrants, more conservative in exercising judgement, and more determined than ever to leave no stone unturned. As a result, the program's already strained scientific resources were even more thinly spread.

The SOR report was not the only jolt to DPR's system in 1990. In January 1990, regulations were promulgated by CDFA governing DPR's compliance with the Permit Reform Act. These regulations set time frames for completion of various actions and required DPR to develop mechanisms to track compliance with them. These regulations, coupled with the SOR report and the influx of data caused by SB 950, slowed the process. In 1990, 459 packages of data submitted to the Medical Toxicology Branch for evaluation took an average of 28.4 days each to clear the station (lower/upper range: 6.4 to 50.5 days). In 1991, the average time required for 570 packages to move through Medical Toxicology had risen to over 40 (lower/upper range: 13.9 to 66.1). The time required for packages to clear other review stations also increased.

DPR's CONTRACT WITH THE PUBLIC

Among DPR's most pressing and difficult tasks will be retaining broad-based public confidence in the integrity and balance of regulatory actions involving pesticides. This will not be easy in California, given the intensity of political discourse in the state and the vehemence with which interest groups pursue their objectives. Moreover, institutional challenges within Cal-EPA will be significant and complex since the use of pesticides affects the quality of the environment -- and people's lives -- in many ways. DPR will have to assess and balance all these impacts in ways which comply with the law, meet public expectations, and make sense.

CHAPTER II: PESTICIDE PRODUCT REGISTRATION IN CALIFORNIA

Before a pesticide product can be registered for use in California, it first must gain a federal registration from EPA. Federal law, data requirements, and regulations therefore largely determine the content of pesticide product label applications submitted to Cal-EPA's Department of Pesticide Regulation.

The basic steps registrants must then take to register EPA-approved pesticide product labels in California include the following:

. Registrants must submit to DPR a complete application -- that is, one containing all the information required to support the type of registration action sought.

- Complete application forms, accompanied by all required data, are then routed through an internal review process, in which each station is asked to make either a "REGISTER" (concurrence) or "DO NOT REGISTER" (non-concurrence) judgement. (Applications for products that are identical to other, already registered products are typically not subject to scientific reviews).

- If no additional questions or requests for data arise and all review stations concur, DPR approves the registration.

Once a pesticide product is registered in California, registrants and pesticide users must abide by the use restrictions, safety precautions, and permitting requirements that DPR imposes to assure adequate margins of safety. Due to the effectiveness of DPR and County Agricultural Commissioner enforcement activities in most counties, custom and commercial applicators and growers tend to take label and other use restrictions seriously.

GETTING INTO THE SYSTEM

DPR requires that an application for a registration action be complete and be accompanied by all required supporting data (or permission to cite data already submitted to DPR by another company), plus the $200 application fee. Different registration actions require different information and supporting data and are subject to different time frames for completion under regulations promulgated in response to the Permit Reform Act: 150 days to complete action on a new active ingredient and 90 days on a new product or label amendment (these specifications are responsive to a lawsuit against the program brought by the National Agricultural Chemicals Association).

Registrants' Perspective on the Registration Process DPR rejects about 50 percent of all applications. This high rejection rate suggests there are significant hurdles to "getting into the system." Such a high rejection rate also represents wasted time and effort, both in DPR and among registrants. It creates a contentious environment and undercuts cooperation between DPR and the affected registrants. DPR needs to understand and, whenever possible, alleviate problems or misunderstandings leading to unduly high rejection rates. But registrants, too, bear responsibility. Specifically, they must more rigorously follow instructions and comply with data requirements if rejection rates are to be lowered.

One component of this study was to conduct a registrant survey regarding perceived strengths and weaknesses of DPR's program (see Appendix 2 for a description and analysis of the industry survey). The survey was widely distributed throughout the registrant community, but only a small percentage of approximately 1,200 registrants responded. It is possible that those registrants who took the time to respond were more likely to be among those who, for one reason or another, have experienced problems with DPR's process.

The most common problems or complaints cited by responding pesticide manufacturers, formulators, and distributors doing business in California are:

- Application packages are rejected for trivial, easily corrected deviations from required formats (such as three copies of a particular page instead of four, missing page numbers, supporting data submitted out of order, or lack of an adequate index to submitted data)

- The working styles of DPR's registration specialists are inconsistent -- for example, some are less communicative than others

- Generally as a result of communications with registrants when reviews are only partially complete, DPR sometimes raises questions which later become moot or have to be revised, making it more difficult and time-consuming for registrants to respond to multiple requests for additional information

- Inconsistent explanations offered by different DPR staff regarding when a given rule or policy applies, or what must be done to comply with it

- Interpretations by DPR scientists regarding what is required to satisfy EPA's regulations, fulfill data requirements (or invoke data waivers), and follow study protocols sometimes differ from EPA's judgements

- DPR requires registrants to provide documents and information from federal EPA which the registrants themselves have not yet received and sometimes have trouble securing from EPA

- Application packages get misdirected or caught "in limbo"

- Excessive time for actions to move through the system

Several examples and variations of the above problems were cited by industry survey respondents and reviewed as part of the study. Nevertheless, data collected in the survey in combination with the positive comments included in the responses indicate that, while problems occur and do warrant attention, they are the exception rather than the rule. Typically:

- Major registrants who have almost daily interactions with DPR and know its rules and requirements express relatively fewer complaints about the process but are more critical of certain DPR policies and scientific inclinations

- Secondary registrants (formulators, specialty chemical manufacturers) who have limited dealings with California experience the highest rejection rates and express the highest level of frustration with what they perceive to be DPR's excessively onerous and rigid process

Complaints tend to be loudest from relatively small companies based outside California selling a limited line of products that meet specialized market, institutional, or pest control needs (for example, companies selling products like sanitizers and disinfectants packaged for and marketed to hospitals or fast food restaurants, powders for home gardeners or greenhouse operators to control certain plant diseases afflicting flowers, or pet soaps and shampoos to deal with ticks and fleas). Among all respondents, those companies which reported the greatest difficulties in complying with DPR's process and requirements tended to be companies selling predominantly nonagricultural products. With only one or two exceptions, they cited as evidence of DPR's unreasonableness the great ease with which they get their products registered in all other states.

DPR's Perspective on Registration Hurdles In an effort to explain the 50 percent rejection rate, DPR itself analyzed a random sample of 110 return letters sent in 1991 to notify registrants of various deficiencies. The results of DPR's analysis (summarized in Table II.l), reinforced by interviews with DPR staff, show that many submissions are deficient in more than one of the following three categories:

1. Label Problems: The label submitted with the application has not been approved by EPA; official notification of EPA approval was not enclosed; six copies of the EPA-approved final printed

label (or printer's proof) were not submitted; the label submitted is not in compliance with EPA policy notices.

2. Data Not Submitted: The data required were not enclosed and/or no letter of authorization was submitted to allow DPR to reference certain other required data that had been submitted previously to DPR by another registrant.

3. Application Errors: The application is incomplete; EPA confidential statement of formula differs from that on DPR application; brand name changes; registration fee was not submitted.

Table 11.1: Basis for Rejection of 110 Registration Applications in 1991

	Applications	Data	Labels
Number of Packages	29	62	89
Percent of 110 Cases	26%	56%	81%

NOTE: Total packages sum to more than 110 because 54 had deficiencies in two or more areas.
SOURCE: Registration Branch review

What the numbers alone do *not* reveal is that DPR's tracking system records clearly indicate rejection rates are highest with registrants/applicants who are inexperienced in submitting applications to DPR. As stated above, rejection rates are much lower (near zero) with basic manufacturers and other registrants who deal regularly with DPR. However, from our survey of registrants, we also noted that even generally successful registrants report what they perceive to be periodic inconsistency in the application of DPR's requirements. Ambiguity in rules, policies, and procedures is another common complaint.

Another important insight emerged from the registrant survey. Several registrants complained about the time it takes for applications to get through DPR's process, saying packages get caught "in limbo." Pressed to offer examples, specific cases cited often involved a registration application for a pesticide about whose use DPR had risk concerns. Rather than denying the application following its initial review, DPR worked with registrants to collect additional data or clarify issues to alleviate DPR's concerns. Sometimes a difference in scientific opinion or judgement lies at the heart of disagreement between DPR, registrants, and EPA.

Rather than "just say no," DPR tries to assess the validity of registrants' arguments and tries to determine the relevance of additional data which registrants submit to make their case. When registrants cite EPA's risk assessments and judgements as reasons why DPR should approve an application, DPR scientists generally want to have a chance to review EPA's risk assessment and decision documents. This step takes additional time because such documents are not routinely shared, nor in many cases are they readily available. These and other steps DPR takes to avoid rejecting an application do take time and do divert DPR's resources from other actions. As a matter of policy and efficiency, DPR perhaps *should* deny applications which it has determined fail to provide sufficient information to demonstrate adequate margins of safety and simply provide a statement of its reasons. Registrants would then be free, of course, to submit another application, accompanied by more information or data responsive to DPR's concerns.

Recommendation #1: Establish an "Ombudsman Office" in the Registration Branch

Despite DPR's generally successful efforts to communicate with the regulated community, problems continue to arise with submissions. DPR needs the internal capacity to more systematically evaluate both the legitimacy, causes, and solutions to recurrent problems. This capacity should consist of people with the clear responsibility, on an ongoing basis, to review procedures in response to complaints so that DPR can assure efficient, fair, and timely resolution of problems. Therefore, *we recommend* that the Registration Branch establish a new position of "Ombudsman" whose responsibilities would include receiving inquiries and complaints from registrants and applicants and then working with branch managers and registration specialists to correct deficiencies in registration submissions as consistently, simply, and expeditiously as possible. In short, when a problem arises or poor communication occurs, the Ombudsman should serve as a single point of contact between DPR and registrants.

Under certain circumstances involving questions of the applicability of California rules and data requirements to a new active ingredient, or a major new use pattern for an already registered active ingredient, *we further recommend* that the Office of the Ombudsman coordinate "up front" meetings between a prospective registrant and DPR registration specialists and scientists. Such meetings would provide companies a chance to alert DPR to new chemistry that might soon become available and could speed up the registration process by assuring that companies understand up front which data requirements they will be asked to satisfy. The Ombudsman should issue a policy letter explaining the information DPR would expect to receive before scheduling such a meeting and the ground rules governing the meeting itself. These rules should strive to assure that the meetings foster efficient communication and not simply provide applicants a chance to lobby DPR staff. This can be done by assuring that a substantive agenda is agreed upon in advance, consistent with the rules governing such meetings. Also, DPR should make it clear that such meetings are advisory and that DPR will have to act upon such requests for meetings in light of other demands on staff resources and its own sense of priorities.

Recommendation #2: Strive for Consistency within DPR and Compatibility with EPA

Most registration actions that DPR evaluates have already been approved by EPA. Registrants complain about the extra time and expense entailed in filling out California forms, because California forms require basically the same information already provided to EPA. For example, DPR has its own form to request the confidential statement of formula for a pesticide product. DPR's form differs in design and format from EPA's but asks for largely identical information. Registrants point out that clerical errors in transferring the information from the EPA to the DPR forms are not entirely avoidable.

We recommend that, whenever possible, DPR either accept photocopies of forms submitted to EPA or design DPR's forms in such a way that identical information can be easily transferred. Likewise, to the full extent possible, DPR should continue its current policy of accepting data previously submitted to EPA in the same form, including reregistration data sets. These procedures will help minimize the time required for registrants to submit to DPR the same information that EPA has already reviewed. As a result, registrants will be able to expedite preparation of California-specific information for DPR which is *not* required by EPA.

Recommendation #3: Provide Training Sessions and Materials for the Regulated Community

We recommend that DPR regularly and formally offer training sessions designed to facilitate timely processing of pesticide product registration applications. These sessions should offer detailed instructions on how to submit applications, which data requirements apply, and how to meet them.

DPR has held two such sessions, both of which were sponsored by industry trade associations. The first, in 1989, was attended by agricultural registrants; the second was held in 1991 and was designed for registrants of home use and industrial pesticide products, and formulators. The sessions were well attended and widely praised. We *recommend* that DPR design general training sessions and educational materials regarding the registration process (required information and format for submissions; how to communicate with DPR regarding the status of each submission). *We further recommend* that DPR develop specialized training and materials in such areas as California-only data requirements and worker safety exposure monitoring methods, methodologies to estimate margins of safety and the effectiveness of proposed risk mitigation measures, and policies governing minimally acceptable margins of safety.

> *"For the first time, I actually understood what they want and how they use the information. I think the training session will help us immediately in reducing problems with our submissions. [DPR] should do more training, including sessions on technical issues.*
>
> -- Training Session Attendee

By offering a regular schedule of annual sessions and timing them properly, DPR can incorporate new issues and solutions to recently encountered problems into the materials and

program in time to help registrants avoid problems in the following year's application cycle. *We recommend* that day-long sessions be run by DPR staff and structured to allow ample time for discussion and interaction. *We further recommend* that attendance fees and charges for information packets and other materials be set by DPR to recover all direct and staff expenses, plus the costs of preparing educational materials. Finally, *we recommend* that written materials be made available at cost to registrants unable to attend.

Recommendation #4: Make Changes in Registration Policy and Procedure in an Annual Cycle

We recommend that DPR coordinate, to the extent possible, the timing of changes in policy, data requirements, and procedures in a once-a-year cycle and communicate to registrants when and how to get information on the changes which may affect them. A key part of this effort should be a communications strategy to increase the likelihood that prospective applicants will learn about the changes well in advance of effective dates -- early enough to assure high compliance rates in the next round of applications. *We further recommend* that DPR's training sessions and educational materials be updated annually.

This recommendation does *not* apply to pesticide product actions and policy statements emanating from the need to impose new risk mitigation measures, nor to notices clarifying existing requirements and policies when questions arise, nor to notices that must be published on a schedule to meet statutory requirements. However, an update and review of all such notices issued in the previous year should be a routine component of the annual training and policy update cycle.

GETTING THROUGH THE SYSTEM

The path an application deemed complete follows through the system is often direct and quick. In some cases, however, it can be full of unexpected turns and detours, few of which speed up the process. In some cases, steps or procedures put in place to comply with a mandate or goal actually compromise attainment of other mandates and goals. For example --

- Adhering to Permit Reform Act time frames to avoid the loss of registration fees adds a fiscal dimension to priority setting -- decisions which *should* be risk-driven

- Completeness of all reviews compromises timeliness and impedes DPR's ability to get new, safer products on the market or to reduce or eliminate risks from those already registered products that turn out to be hazardous

- Efforts to limit risk mitigation measures to only the counties where they are needed complicates enforcement activities

Sometimes registrants get caught in a cross fire between DPR and EPA or between branches within DPR. In a few cases, registrants have been confronted with having to choose which agency's requirements to violate. For example, one respondent to the industry survey recounted the story of a label amendment involving a change in toxicity category which had been accepted by EPA -- thereby invalidating its old label. Upon reviewing the same application, DPR was unable to approve the new label but would have allowed the product to remain in use under the old label. According to the registrant --

> This put the production/sale of the product in limbo. We cannot put either label on the product without being out of compliance somewhere. The peculiar aspect of this action is that the data that were found unacceptable [by DPR] were not the data submitted to support the action; those data were found acceptable. Rather, this label amendment provided an opportunity for DPR to "dig into" other aspects of the product and request additional data when they had not been required by EPA.

Many registration applications move through DPR's system quickly. Those moving slowly typically raise questions about levels of risk, the adequacy of risk mitigation efforts, or degree of compliance with EPA policies. Major new uses or label amendments for highly toxic materials typically receive close scrutiny, as do all new active ingredients. In many cases, DPR focuses much more closely than EPA on the acute data and risks associated with formulated end-use products and, in so doing, discovers that the data in support of many EPA-approved labels either do not meet EPA's own requirements or raise risk concerns that DPR is unwilling to accept without further study and/or risk mitigation measures.

When deficiencies are found and addressed by DPR, in effect the program is highlighting long-standing problems with existing registrations and labels that EPA is striving to rectify through federal reregistration. But, while EPA's schedule for completing reregistration stretches into the next decade, California law and policies force DPR to confront and deal with such problems associated with a given registration application when they first arise.

About 9,000 registrations are approved or renewed by DPR annually. The vast majority -- some 7,500 renewals -- require no new data or scientific review and move through the system in a matter of days, provided they are accompanied by the correct fee. Each year, registrants seek non-substantive label changes covering about 1,000 existing registrations, nearly all of which move through the system in a few weeks. And every year, about 1,500 new product registrations are granted and about 1,500 existing registrations are dropped.

TYPES OF PESTICIDE REGISTRATIONS

Basic FIFRA §3 Registrations

Pesticide products registered in California must first be registered by EPA, generally under §3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Section 3 contains EPA's authority to grant full and conditional registrations. DPR requires §3 label applicants to provide a copy of the final EPA-approved label. DPR has analogous authority in California to grant conditional registrations, often used to provide applicants time to develop California-only worker safety, efficacy, and environmental fate data. DPR grants full registrations to --

* ***New active ingredients***

* ***New products containing currently registered active ingredients***

* ***Already registered products (renewed on an annual basis)***

* ***Label amendments***

Changes in use pattern requiring approved label amendments include: crop; locale; timing, rate, and number of applications; pre-harvest intervals; concentration of active ingredient or inert ingredients; and safety precautions. Label amendments for existing products are the most common registration action that requires DPR to review data and, in a few cases, to conduct risk assessments.

FIFRA §5 -- Experimental Use Permit (EUPs)

An EUP allows experimental field-scale use. An application for an EUP for a new active ingredient triggers DPR's first review of data and weighing of risks associated with a proposed pesticide use. EUP applications increasingly are accompanied by the basic chemistry and toxicological data needed to support full §3 registrations. DPR encourages registrants to submit as much data as possible at the EUP phase. Many smaller EUP's are handled as state research authorizations instead of registrations.

State Approved Labels

FIFRA delegates to states the authority to issue two types of state-only registrations. EPA subsequently reviews and approves the state approved labels --

* ***FIFRA §18 — "Emergency Exemptions"***

Granted when a state finds that an emergency exists, no effective alternatives are available, and the proposed pesticide will be safe and effective. §18s are generally accompanied by an action level in lieu of a permanent residue tolerance.

* ***FIFRA §24(c) — "Special Local Need"***

Applications for SLN labels are approved by DPR. They cover pesticide active ingredients already registered under §3. Section 24(c) labels allow a pesticide to be used in a state, or a set of counties within a state, in additional places, on additional crops, or in a different way than provided for under the terms contained on the federal label. Again, federal regulations require that there be no viable alternatives. Unlike section 18s, SLN labels are granted if special local need criteria are met, but only when either a tolerance, or an exemption from having a tolerance has been granted by EPA.

TYPES OF REGULATORY ACTIONS

Reevaluation

DPR may initiate a *reevaluation* of the safety of a pesticide product, or set of products, containing a single active ingredient when the Director receives new information that "an economic poison may have caused, or is likely to cause, a significant adverse impact, or that indicates there is an alternative that may significantly reduce an adverse environmental impact." The process is roughly analogous to EPA's special reviews, although procedurally it is neither as complex nor formal. Since passage of SB 950 and establishment of the Adverse Effects Advisory Panel that sets priorities for risk assessment when SB 950 data are received, few pesticides have progressed through the reevaluation process called for in §6220 of the California Code of Regulations on account of chronic toxicology concerns. Instead, pesticides already in reevaluation have been "transferred" to the top priority list of chemicals for risk assessment and risk mitigation under SB 950. §13129(a) of the Food and Agriculture Code, passed as part of SB 950, calls upon the Director to "take cancellation or suspension action" against products containing a pesticide active ingredient that "presents significant adverse health effects...."

Regulations to Reduce Risk

When DPR concludes that a proposed label poses unacceptable risks, it can either deny the registration or impose additional risk mitigation measures in California-only regulations, enforceable through the county agricultural commissioners' permitting process. While this process entails significant administrative and enforcement costs that are growing more difficult to cover, it has made possible significant progress in balancing pesticide risks and benefits.

Policy Letters

DPR strives to help pesticide registrants, applicators, and growers understand DPR rules and regulations. Policy letters can address issues arising from use of a particular pesticide, or may be generic.

2,000-2,400 DPR actions annually involve new products or substantive label amendments. These actions are described in Table II.2 (see next page), which presents information on a typical DPR program year. Table II.2 covers registration and scientific review activities relevant to decisions on distinct registration applications, as well as general data reviews for active ingredients. It does *not* encompass much of DPR's data call-in and review activities nor field level worker-safety, environmental monitoring and pest management, and enforcement efforts. The table displays estimated percentages of DPR activity devoted to different types of actions, time frames for completion, and common reasons why some actions are delayed.

Table II.2: DPR Registration and Scientific Review Activity: Type, Number, and Timing of Actions in a Typical Year

Type of Action	Number	Percent of DPR Effort	Time Ranges to Complete	Common Reasons for Delay
Data Call-Ins	1800	15-25	N/A	N/A
New Product Registration	1520	27-45		Lack of efficacy data; unmitigated risk concerns
Products containing new a.i.	(20)	(20-30)	16-24 months	
New brand names/distributors*	(1000)	(2-5)	l-2 months*	
New products needing scientific reviews	(500)	(5-10)	4-8 months	
Label Amendments	1700	16-27		Label problems; lack of California-only data
Substantive changes	(700)	(15-25)	3-12 months	
Nonsubstantive changes	(1000)	(l-2)	l-2 months	
Section 24(c)	180	4-6	2-5 months	Need to generate California efficacy or worker safety data
Section 18	35	2-4	1-3 months**	Lack of economic data; inadequate documentation of emergency or no alternatives
Reevaluation	l-4	2-6	2-4 years	Need for additional data; higher priority demands on staff scientists
"Chemical of the Year Crisis"	l-2	5-20	6-18 months	Lack of data to resolve immediate health concerns or economic impacts

NOTES: Total number of actions are estimates (averages reflecting the past five years of DPR program activity). The time frames and reasons for delay are taken from actual case records in DPR's tracking system, responses to the industry survey, and interviews with DPR registration specialists.

* EPA typically accepts a change in brand name automatically upon receipt of a letter from the registrant. California law requires registrants to submit a whole new application, accompanied by another $200 fee.

** Includes EPA's 50-day review.

SOURCES: Review of DPR records, staff interviews, and the registrant surveys (see Appendix 2).

Timeliness in Entering the California Market In the industry survey undertaken as part of this project, several registrants complained about significant losses in sales revenue when DPR requirements, or the time DPR needs to carry out reviews and make decisions, postpones the date when a product can be legally used in California, Many instances were documented in which a full production season, and sometimes two, were lost. Three reasons typically cause DPR to reject current applications and/or defer decisions:

- Waiting for acceptable data to fill mandatory California-only data requirements, especially efficacy and worker safety related data

- The standard set forth in California law for judging the adequacy of a study -- "complete, valid, and adequate" to reach a safety judgement -- is more rigorous in practice than EPA's standard, under which EPA will often accept a study as filling a data gap (sometimes with other available information) but defer carrying out a risk assessment based on the data until called for through reregistration or in a special review

- Concerns about risks to applicators, workers, or the environment which do not seem adequately addressed given currently available data

In particular, registrants complain about the requirement to develop efficacy data in California to cover a new closely-related crop or pest for products that have a proven track record, or which have been changed in ways that would not alter performance. Moreover, demonstrating efficacy in the "spray and count" type of efficacy field study required by DPR, in compliance with EPA study protocols, may be inappropriate for certain biological products which work not by killing pests but by disrupting normal behavior patterns. To maximize the efficacy of pheromone confusion products, for example, they need to be used over large areas and in the context of a carefully managed crop protection system. These and other pest management *system* factors, crucial to efficacy for many biochemical pesticide products, are not adequately accounted for in EPA's outmoded efficacy data requirements and study protocols. DPR recognizes this shortcoming but remains obliged to follow EPA's data requirements. In the case of biorational pesticides, DPR has sought and adopted suggestions from registrants regarding how efficacy trials should be designed.

The bottom line, as Table II.3 illustrates, is that most products move through DPR's system as fast as, or faster than, through EPA's. Based on examples cited by registrants responding to the industry survey, average times in months are shown for completion of the same registration action by EPA and DPR, as well as the time span between EPA registration and use in most other states, and availability for use in California. Data in Table II.3 provide a valid basis for comparison because registrants were instructed in the survey to report information on the first three actions in each category completed in 1990 and in 1991 (for a total of up to six actions). Few respondents

reported more than six actions in any one category, so the sample of cases cited can be viewed as an accurate reflection of "average" conditions.

Table II.3: Time to Complete Actions by EPA and DPR, as Reported by Respondents to Industry Survey

Type of Action	Number	Months to Complete EPA : DPR	Months from EPA Approval to Use in California
New Products	28	17.2 : 7.5	14.9
Label Amendment	17	8 :3	7.4
New Active Ingredient	7	16.6 : 16.7	22.7
Change in Ownership	5	5.2 : 0.9	4.0
Change in Formula	5	6.6 : 3.8	7.8

NOTE: The column "Months from EPA Approval to Use in California" includes the average time between approval by EPA and submission to DPR, any time that passes before DPR accepts a package as complete, time needed for DPR review and action, plus one month for posting. These figures were computed using responses from the industry survey which provided the necessary dates and which indicated typical registrant actions. Responses which reflected unusual circumstances and/or purposeful marketing decisions were not included.

SOURCE: Responses to industry survey (see Appendix 2)

The EPA-approval-to-California-use time span warrants special attention and is a major concern to registrants and growers. Environmentalists should also take notice, since most safer pesticide products, including Bt, pheromone confusion products, neem, herbicidal soaps, and other biorational pesticides also tend to move slowly through DPR's process. The time span between EPA approval and use in California has three components:

- The time needed for a registrant to develop and submit a complete, acceptable application to DPR after receipt of an EPA label

- The time DPR needs to review and act upon the application (second set of numbers in the middle column of Table II.3)

- Regulations pursuant to the California Environmental Quality Act which require a 30-day posting period after an application is approved to allow for public comments, prior to the date a pesticide product can be legally used (registrants report that this requirement typically causes about a 45-day delay)

Recommendation #5: Cut by At Least One-half over the Next Two Years the Average Time between EPA-approval and Use in California for New Active Ingredients and New Products

DPR bears only partial responsibility for the delay between EPA-approval and California registration. Sometimes, registrants fail to plan ahead adequately and do not initiate studies soon enough to generate data they know DPR has to have. Some registrants are not primarily interested in the California market and so put off developing California applications and data. Still, there is much DPR can and should do in getting new products -- which will generally be safer than older, still registered products -- onto the market faster,

We recommend that DPR strive by 1994 to approve applications involving new active ingredients within eight months, on average, and to assure that all new active ingredients get through the system (or be denied) in no more than 12 months. Such time frames -- tight for new active ingredients, but realistic -- should be embodied in a change from the current 150 days for final action in DPR's Permit Reform Act regulations to 240 days.

DPR should continuously strive to convince registrants that its process and policies, while rigorous and thorough, are nonetheless orderly and science-based. It should do all it can to clearly and frequently communicate its requirements and policies in an effort to demystify the process and heighten confidence that outcomes can be predicted. It can work toward these goals by implementing several new policies and procedures addressed earlier -- the Ombudsman office, "up front" meetings, training sessions, and clear articulation of data requirements and policies.

In the case of new active ingredients, *we recommend* that DPR develop procedures and policies that either accept with minimal oversight EPA reviews of core toxicology, residue chemistry, and environmental fate data, and/or carry out its own reviews early in the regulatory review process (such as at the Experimental Use Permit stage). Such steps will speed up progress through DPR review stations when the full application is received and help identify any scientific questions DPR will ask registrants to clarify. It is likely that DPR will have to overcome both

statutory constraints and political resistance in acting upon this recommendation. For these reasons, DPR and Cal-EPA must persuasively articulate the potential benefits in terms of lessened use of more hazardous materials associated with getting new products registered more quickly, particularly safer pesticide products.

> *"Given EPA's performance [in reviewing core toxicology studies on new active ingredients], we should not be in a big hurry to trade known hazards for unknown* ***ones.*** *"*
>
> -- California Public Health Scientist

A third option to speed up the process would be for DPR and EPA to carry out concurrent reviews. If this option is tried, the reviews should be set up to avoid situations in which registrants can play DPR and EPA scientists off against each other. Such reviews should not just be done concurrently, they should also be done collaboratively so that technical issues and scientific judgements can be resolved internally without undue pressure from registrants.

One way DPR could lend structure and predictability to the process of deciding which new active ingredients warrant in-depth DPR reviews, and for which studies, would be to establish toxicological, chemical, exposure, and use-pattern related criteria governing the circumstances when EPA reviews and risk assessments might be relied upon heavily by DPR in expediting its own decision making. Such criteria are under discussion at the federal level, within both EPA and the Congress, in the context of "safer" pesticide policy proposals. We *recommend* that DPR experiment for two years with this approach and begin by publishing a set of criteria. Registrants should then be given the option of asking for expedited review of new active ingredient data packages. These requests would need to be accompanied by data and the reasons why the registrant believes its new active ingredient meets the criteria, along with copies of EPA's reviews of the chemical's basic data package and EPA's decision documents summarizing its risk assessment.

We offer an additional two-part recommendation applicable to proposed label amendments for adding a new use, altering a use pattern, or seeking other non-substantive label changes. The first part of the recommendation should not be acted upon without comparable action on the second.

Part 1 In the case of relatively minor label amendments involving a pesticide product containing inert or active ingredient(s) with a solid record of safe, efficacious use in California, we *recommend* that DPR routinely accept -- without in-depth scientific review -- EPA's decisions regarding such label changes. Such amendments will typically include changes in brand names, changes in company ownership, or other trivial clarifications or additions to a product label that will have little or no impact on use patterns or risks in California.

Part 2 But we *also recommend*, in cases where label changes entail adding a new crop, a new target pest, or changing use patterns or where non-substantive changes are requested for a pesticide product that contains an inert or active ingredient that has

caused problems in California or for which there is new evidence of the potential to cause problems -- whether human health, environmental, or efficacy -- that DPR continue its current policy of *not* approving label amendments (even minor ones) until outstanding risk-related concerns are alleviated.

Last, we recommend that DPR waive or change the requirement for California-specific efficacy data when an amended label includes a new target pest closely related to other target pests already on the label, or a new crop closely related to other crops. For actions with little bearing on a pesticide product's efficacy, DPR should strive to complete its approval action within one month, on average. This would free up a portion of DPR registration and scientific resources to be redirected to reviewing applications for use patterns that do raise significant concerns regarding efficacy or risks in California which have not been adequately evaluated by EPA nor addressed on product labels.

"We much prefer DPR's system of routing all communication through one registration specialist. It saves time and helps build trust and understanding. EPA's system... is very tough to keep track of."
-- Industry Survey Respondent

Steps in the Registration Process Each application for registration is assigned to a registration specialist whose job it is to route the package through the process and assure that each review station has the data it needs to carry out its assessment. The registration specialist also compiles a docket recording the conclusions reached as the review progresses. When DPR needs additional information -- if, for example, a question arises regarding a study protocol -- the review station needing that information asks the registration specialist to contact the registrant.

This system works well to the extent that it channels all DPR-registrant communication through the registration specialist assigned to the application. Moreover, each of the approximately 1,200 registrants is assigned to one specialist, a policy which has helped foster clear and efficient communication. On the other hand, this approach can also lead to trouble when a registration specialist and a company representative begin to have problems working together cooperatively.

There is no "normal" route through the process. The stations where reviews are relatively more straightforward, especially those within the Registration Branch -- biology, chemistry, entomology, microbiology, and plant physiology -- often are among the first to receive application packages. Thus, the initial reviews of an application tend to proceed on schedule. Review stations with big backlogs are initially avoided but, beyond this attempt to avoid making backlogs worse, routing decisions are not systematic. Table II.4 summarizes the functions of the basic review stations and displays data on the number of packages and average time required for packages to clear each station in 1991.

Table II.4: Steps in the Review Process and 1991 Program Performance

	Number of:	Time in Station (days)
	Reviewers:Packages	Mean : Lower/Upper Range
Registration		
Chemistry	3 : 576	18.1 : 1.4/34.7
Microbiology	2 : 247	17.8 : 6.6/29.0
Plant & Disease Protection	1 : 336	16.4 : 6.1/26.6
Plant Physiology	2 : 174	10.9 : 0.0/22.6
Fish and Wildlife	1 : 184	9.4 : 0.0/19.6
Medical Toxicology	6 : 570	40.0 : 13.9/66.1
Worker Health and Safety	2 : 376	20.2 : 0.0/41.9
Total Time (all stations)		132.8

NOTE: Worker Health and Safety packages and time in station data are for 1990.
SOURCE: Time in station and number of packages from DPR Annual Tracking Report, personnel numbers from DPR organization charts and the Governor's Budget FY 90/91.

DPR program managers contend that between 93 and 99 percent of the mean time in station, as shown in Table II.4 above, actually represents delay caused by backlogs rather than time needed to carry out reviews. Accordingly, of the average 132.8 days it took in 1991 for a package to move through evaluation, over 120 days represented time that the packages were caught up in backlog-driven delays. Clearly, the timeliness of DPR actions could be greatly enhanced with no loss in quality. Through a combination of policy, budgetary, and management efforts, DPR could markedly reduce the volume of packages and actions tied up in backlogs and, once caught up, keep the volume from rebuilding by altering the nature of the review process or the number of people carrying out reviews, or both.

Workload DPR's workload falls into three basic categories: registration actions, data call-in and review, and dealing with the outside world (including other agencies of the state and federal government). Workload in the first category, registration, is driven by the number of applications received and is product specific. Workload in the second category, data call-in and review,

emanates largely from legislative mandates, affects both active ingredients generically and formulated products, and is not tied to a given registration action. DPR staff doing legislatively driven data call-in and review work get involved with product registrations to varying degrees.

The third category of DPR work -- what might be called "exogenous shocks" -- is the most unpredictable. For that reason alone, if for no other, it is a source of growing concern if DPR is to deal successfully with its routine work. "Exogenous shocks" include such things as the "Chemical of the Year" phenomenon (such as the metam-sodium train spill in July 1991), budget gridlock and uncertainty, poisoning incidents, unexpected EPA actions, political pressure to either register or cancel certain products, or new initiatives taken by other agencies which affect pest control efforts.

Since 1990, DPR has handled about 40,000 submissions of data, registration applications, requests for state registrations, and other sorts of actions. Dictated by new state laws, the volume of data needed to apply for and retain most types of registrations has more than doubled in the last decade. The following examples of recent additions to the California Food and Agriculture Code are illustrative:

- Article 14 was added by the "Birth Defect Prevention Act of 1984" (SB 950/Petris) and requires registrants to fill 10 core toxicology data requirements. This process is nearly complete on an initial list of 200 active ingredients, and DPR is now starting the process on what may become up to another 400.

- Article 15 arose from "The Pesticide Contamination Prevention Act of 1985" (AB 2021/Connelly) and requires DPR to collect extensive data needed to estimate the leaching potential and environmental fate of pesticides.

- Section 13131 was added in 1991 by AB 2161 (Bronzan) and requires DPR to carry out a number of new actions, including dietary risk assessments.

- AB 1807, passed in 1983, requires DPR to monitor and evaluate risks associated with certain pesticides that are found in the ambient air.

Exogenous shocks include administrative actions by other California agencies. Typically, these actions are triggered by laws, including voter initiatives. For example:

* *State Water Resources Control Board* challenged DPR to meet maximum contaminant levels for rice herbicides in the Sacramento River (see more discussion of this issue in Chapter V)

* *Air Resources Board* has called for restrictions on volatile organic compounds, including pesticides, that appear in a number of products. The ARB monitored schools and residential areas in the San Joaquin Valley and found the soil fumigant Telone at unacceptably high levels. Local air resources boards are also beginning to show an interest in imposing regulatory controls on certain pesticides. For example, the Monterey Bay Unified Air Pollution Control District wants to control the way methyl bromide can be applied in that area for purposes of protecting the ozone layer.

* *EPA*, in order to comply with the 1986 Montreal Accords, may cancel or severely restrict soil fumigant uses of methyl bromide by or about the year 2000. Methyl bromide is about 60 percent as efficient as chlorofluorocarbons in thinning the ozone layer.

Gridlock Growing workload relative to staff size places a premium on administrative efficiency. DPR's workload is undeniably growing, so it will face increasingly pervasive gridlock to the extent it fails to develop and adhere to priority setting mechanisms in deploying its scientific and analytical resources.

As it worsens, gridlock will have several negative consequences. It will slow down the approval process for safer pest control products and other new active ingredients. It will reduce the number of pesticide products that DPR can realistically move through reevaluation and will stretch out the time between data submission, review, risk assessment, and the imposition of risk mitigation measures. It will heighten tensions with registrants, force growers to suffer possibly avoidable crop losses or incur higher than necessary crop protection costs, and breed skepticism among environmentalists who are looking for decisive action quickly whenever new data or incidents suggest the presence of unacceptable risks.

DPR also sometimes gets bogged down in complying with legislative mandates that make little sense relative to one or more of its missions. Furthermore, laws sometimes compel DPR to impose requirements which are hard to justify economically. In other cases, DPR lacks the tools it needs to accomplish change in how pesticides are incorporated within crop protection systems.

Impact of the Permit Reform Act The Permit Reform Act requires DPR to communicate to registrants whether their applications are "complete or deficient" within 120 days for new active ingredients, 60 days for most types of actions, and 30 days for renewals. DPR is then given 30 days more for each type of action to "approve or deny [the] permit."

These time frames arose from and reflect conditions in the 1970s and early 1980s when DPR analyzed only summaries of a few studies on each application. The time frames in the regulations evolved from an industry lawsuit alleging too slow a pace in completing actions. For applications

that warrant DPR review, these time frames are unrealistic in the 1990s because there is so much more data and so many more kinds of risk that must be evaluated in support of a decision to grant a registration, DPR should strive to meet them *on average* rather than on a per application basis by limiting the scope of reviews on pesticide products that DPR knows a lot about and which rarely cause problems. It will need and *should* take more time in other cases.

Because reviews and decisions are rarely completed within the allotted time to approve or deny registrations, DPR complies with the act by sending a letter to applicants reporting the status of its review. Registration specialists try to manage the process so that a reasonably thorough report can be sent at the end of the 60 or 120 days. They try to route packages so that as many review stations as possible have seen the application. Often these status report letters also contain requests for more data or clarification of certain information submitted in support of a package. Identification of deficiencies or requests for new data "stop the clock" for purposes of compliance with Permit Reform Act time frames. When the applicant does not reply to this notification and/or when DPR formally denies an application because of unmitigated risk concerns, the registrant must submit a new application to continue pursuing the label, automatically starting a new "clock" under the Permit Reform Act -- and requiring another $200 application fee.

No Relief from Uncertainty Despite its best efforts, DPR is often thrust into the unknown and has to go beyond routine procedures to deal with uncertainty -- whether scientific or political. These challenges test DPR's analytical expertise and its management skills and systems. Unfortunately, scientific uncertainty promises to remain part of the pesticide regulatory process for the foreseeable future. Appendix *6, Improving the Science Base for Regulation,* outlines several essential areas in which regulators may be able to improve risk assessment methodologies and knowledge of the environmental fate of pesticides and to gain new insights into how people, pests, and pesticides interact. These efforts are important but will never completely remove uncertainty regarding the actual risks of pesticide use.

Recommendation #6: Amend the Permit Reform Act and/or Modify Its Implementing Regulations

The impact of the Permit Reform Act on pesticide regulation in California is a good example of unintended consequences. This generic statute strives to require that regulatory agencies treat all citizens and businesses on a "first come, first served" basis. Not allowing a given application to "break into line" evolved into a DPR policy, driven by the need to comply with Permit Reform Act regulations. DPR's failure to comply with the time frames would place registrants in a position to request a refund of their $200 application fee. DPR has worked assiduously to avoid this outcome.

If all pesticides were created equal and posed roughly comparable technical questions as they move through the process, this "no breaking into line" policy might make sense. But DPR

specialists know that all pesticides are *not* equal, either in terms of the risk of using them or the difficulty in reaching registration decisions about them. DPR staff need a greater degree of flexibility to accelerate progress through the system for safer pesticide products that can help growers, nonagricultural pesticide users, and the general public move toward more effective and affordable ways to control pests.

We recommend that DPR seek an amendment to the Permit Reform Act or modify existing regulations to establish more realistic time frames in which to complete actions and to set goals on the basis of the *average* time needed to complete a particular type of action. This change would leave DPR free to adjust the intensity of individual reviews. DPR should also establish an exemption from the first come, first served principle of registration action management for safer pesticides (see the end of this chapter, or Appendix 8 [Glossary], for definitions of "safer," "high risk," and other terms and concepts used throughout this report). This exemption would produce two important public health and environmental protection benefits:

- Safer pesticide products would reach the market sooner
- DPR could more effectively target its data collection efforts on high risk products and use patterns for purposes of risk assessment and crafting of risk mitigation measures

Recommendation #7: Overcome Gridlock and Delays by Periodically Purging the System of Backlogs

An unlikely but straightforward solution to gridlock would be for the Governor and Legislature to provide DPR with adequate resources to match staff levels to workload needs. This step is unlikely because of California's severe budgetary problems, and because views diverge so fundamentally among key interest groups. Until there is a closer match between resources and work, DPR should take minimally disruptive steps to loosen the grip of gridlock.

We recommend that DPR develop mechanisms to move applications which raise no significant new risk concerns and which involve an active ingredient which DPR feels it knows a lot about through the process well *within* current Permit Reform Act time frames. In such cases, which would not include applications for new active ingredients, *we recommend* specifically that --

- A team of experienced DPR scientists and registration specialists meet regularly to determine which applications should be designated as prospectively "low risk," before the packages begin moving through the system

- Each review station should make a preliminary review of low risk (or safer) pesticide product packages within seven days, forwarding all those for which no basis for concern was identified in the initial review

- When the initial seven day review raises concerns warranting more in-depth review, stations should have no more than 30 days to reach a judgement regarding whether to recommend registration, make a request for further data, or recommend a comprehensive risk assessment to determine the need for risk mitigation measures

- Each station should reduce its backlog of submissions needing review at the beginning of each month to *no more than* one-quarter of its monthly average number of submissions evaluated over the preceding 12 months (each station should be given the responsibility of developing the best means to accomplish this objective by streamlining reviews in a way that does not compromise other goals)

In conjunction with the above steps, *we also recommend* that DPR develop, test, and refine mechanisms to purge the system of backlogs at least semi-annually, and preferably quarterly or even monthly. One step toward this goal might be to announce two moratoria per year, each lasting two weeks, during which no new registration applications would be processed. During these periods, to be scheduled before and after annual spikes in the number of new registration applications, Registration Branch staff would focus on clearing away backlogs, conducting registrant workshops, and assessing the need for internal policy development. Scientific staff and review stations should use these times to work their backlogs down to or below target levels -- no more than one-quarter of an average monthly number of submissions in need of evaluation -- and to assess internal management issues.

We recommend that DPR seek from the Governor and Legislature authority to change its fee and/or mill tax rate structures so that it can more systematically alleviate the factors contributing to backlogs. Fees and the mill tax together should generate enough resources to complete actions and get through the process of implementing statutory mandates such as SB 950 on a more timely basis. Penalties and resubmittal fees should be set high enough to serve as a deterrent to applicants who waste DPR's time by submitting incomplete or erroneous packages.

Fees for various types of actions and submissions should be adjusted so that they more equitably and realistically reflect the work entailed. All actions taken by DPR, including label amendments, should entail a fee. If problems persist in financing DPR's program, DPR might also seek authorization to impose resubmittal fees of no less than $100 and up to one-half the applicable fee on packages which are rejected as incomplete. A resubmittal fee might also be applied when registrants ask DPR to review additional data which it feels will alter DPR's assessment of risks or exposure levels.

Recommendation #8: Establish Procedures for Clear and Efficient Communication with Registrants on Pending Applications

Registration specialists should be encouraged to seek resolution of nonsubstantive issues in the most direct way possible, minimizing the time and expense required to resolve them. The Ombudsman position we recommended earlier clearly has a constructive role to play here. Likewise, dialogue between DPR scientists and applicants can also prove helpful in expediting resolution of many sorts of issues that might otherwise take considerable effort to resolve.

We recommend that DPR review and revise as needed Policy Letter 87-2, along with other policies which shape current procedures for registration specialists to follow when communicating with registrants regarding pending applications. For example, when scientific uncertainties arise which necessitate requests from DPR for more information, communication procedures should be designed to --

* Assure that all scientific issues and data requests have been determined and clearly communicated to registrants

- Describe the basis for concern leading to the request for further information

- Explain the risk-related criteria that are normally applied in reaching comparable judgements regarding the acceptability of risk

Recommendation #9: Customize Policies and Procedures to Apply Data Requests Systematically and Achieve Risk Mitigation Targets Uniformly

After the release of a report by the Senate Office of Research (SOR) in March 1990, DPR became stricter in insisting that all data gaps and risk concerns be resolved before granting registrations. Some registrants were caught by surprise when DPR raised a range of generic questions regarding the availability and adequacy of data on products with long-standing registrations whose renewal had received little notice in previous years. In one case involving a sulfur product reformulated in a way that reduced the sulfur content by less than 1 percent, DPR's new policy triggered a decision to carry out a thorough review of the product, including a request for additional studies.

We recommend that DPR strive to become more systematic in distinguishing between a change in policy or procedure that should be adopted uniformly and applied across all registered products from actions or requirements properly directed toward a single pesticide product. For example, changes in policy governing acceptable levels of risk or adoption of a new model for estimating a particular type of risk should apply to all products and be imposed across all products within a given annual cycle of registration activity. Such changes should be announced well before the next registration cycle begins and included in annual registrant training workshops. DPR also

needs to retain the existing policies and procedures that allow it to customize data requests and regulatory actions which should apply only to a single pesticide product, or a small set of products.

Recommendation #l0: Change the "No Alternatives" Rule in Cases Where an Additional Product Will Reduce Risks and Promote Sustainable Crop Protection Systems

State and federal laws require that several DPR decisions be predicated on a finding by the Director that no viable alternative pesticides are registered for the same use or that no viable biological or cultural pest control practice is available. Examples include --

* FIFRA Section 18 "Emergency Exemptions"

- "Special Local Need" labels under FIFRA's Section 24(c)

- Deferral of suspension under the state SB 950/SB550 process

This requirement, imposed on DPR by statutes and EPA regulations, creates a *defacto* policy encouraging the use of a single pesticide to control a given pest in a given environment. By so doing, it sets the stage for possibly excessive exposure in certain areas and for the emergence of genetic pesticidal resistance. Moreover, progress in developing biointensive IPM systems depends upon access to a *wider* rather than *narrower* range of pesticides and control options.

Insisting on *no* alternatives may set the stage for serious ecological and environmental problems. When all or most growers in a region are constrained to only one viable choice in a season or area where pest infestations are particularly bad, the total volume of one pesticide applied can overwhelm the assimilative capacity of the environment and cause adverse human health effects, fish and bird kills, and environmental degradation. The no-alternatives policy is especially counterproductive in its bias against biochemical pesticides that only work within the context of a pest management system, which generally *combines* chemical and biological pest control.

As the debate at the national level unfolds on EPA's proposed "safer pesticide policy," *we recommend* that the Governor and Legislature enact state legislation and memorialize the President and Congress to amend FIFRA to provide an exemption to the no-alternatives rule in cases where the availability of additional products will make it possible to reduce risks and promote sustainable crop protection systems.

Recommendation #ll: Change or Waive Efficacy Data Requirements So That Useful Information Is Produced and So That Entry to the California Market Is Not Delayed

Some of the efficacy data on agricultural products generated in compliance with EPA study protocols and submitted to DPR is of limited use. The data provide information about a pesticide's

ability to kill its target under *prescribed* field conditions but do not provide insight under ***actual*** field conditions into the product's effectiveness in promoting safe, effective, and affordable pest control systems. Furthermore, the data do not address the myriad interactions between a pesticide, its target, the plant, and other beneficial species. In the case of biochemicals, such as pheromones, current "spray and count" efficacy trials are often meaningless, because these products are intended to manage pest populations rather than kill individual organisms.

Efficacy data are needed in many agricultural circumstances and play an important role in most nonagricultural use patterns, especially disinfectants and sanitizers. For this reason, EPA and DPR should continue to require and assess a core set of efficacy data on new active ingredients to combat the prospect, feared by some DPR experts, that the number of ineffective pesticide products proposed for registration will grow. On the other hand, current efficacy data requirements need revision in order to prevent unintended delays in getting safer pesticides on the market.

We recommend that when DPR determines the need for efficacy data, the requirements be tailored in light of the specific properties of a product and the data collected following study protocols carried out to the fullest extent possible under ***actual*** conditions of field use. Different products will raise variable degrees of concern about efficacy; new data requirements should be applied in a common sense, tiered fashion. Efficacy data on one crop-product-pest combination should suffice for another similar combination, unless there is some change in the formulation or use pattern that raises new questions about efficacy. Laboratory data on the impacts on non-target species should be accepted whenever possible.

We also recommend that when DPR asks registrants to generate new efficacy data for an already registered product, DPR also ask registrants to fill the requirement in the one to three years ***after*** the registration is granted. Until such data have been generated and found acceptable, the registration granted by DPR should be conditional.

Both DPR and EPA experts acknowledge that efficacy data requirements need to be reviewed and updated for any product -- agricultural or nonagricultural -- for which it is difficult or impossible to observe directly whether the product has performed its intended function. While it would be preferable for EPA to take on this task, the federal agency currently places a very low priority on the long-awaited revision of its efficacy and benefits data requirements and so may need to be spurred on by the offer of carrying out such a review jointly with DPR.

> *"[The soil fumigant] DBCP was applied for years 'on faith, 'because nematode damage 'might not show up until its too late.' Despite predictions of 'the end **of** California agriculture as we know it,' production did not miss a beat. Nor has it after DPR nailed [the soil fumigants] 1,2-D and, most recently, Telone. That's why we need intelligent, scientifically-based efficacy data. Maybe pesticides aren't as necessary as a lot of people claim. It's time **for an** honest assessment."*
>
> -- State Employee
> (expert in pesticide use and risks)

The notion of benefits, moreover, surely encompasses a pesticide's impact on beneficial species, secondary pest problems, and the prospect of resistance. *We recommend* that DPR start to utilize systematically a rarely used part of the California Food and Agriculture Code, Section 6189 pertaining to "effect on pest management." This simple but appropriate section authorizes the director to request data "concerning any adverse effect of the [pesticide] product on pest management systems for that crop." While the marketplace may eventually take care of efficacy-related problems, DPR should strive to identify and respond to pest management system-based problems with a pesticide's performance, particularly when a lack of efficacy leads to the need for additional pesticide use.

DPR should also encourage EPA, when it reassesses its existing efficacy data requirements and field study protocols, to expand its notion of efficacy from a narrow "spray and count" formulation to a broader, ecologically-based assessment of a product's impact on pest management systems as a whole, studied under actual conditions of field use.

Important Cautions DPR should *not* try to impose existing or new efficacy data requirements comprehensively, because it would be very costly to do so and the information would too often be of limited use. But DPR *should* adopt new policies requiring registrants to routinely submit, under the adverse effects reporting policy, information they have gained that documents the existence of "efficacy" problems with a pesticide product in the field. Moreover, DPR should develop routine channels of communication to assure that such information is also made available to extension pest management specialists and other researchers, crop consultants, pest control advisors (PCAs),and others working directly with growers in pest management efforts.

One key purpose of requiring such information and data to be submitted to DPR is to give Environmental Monitoring and Pest Management Branch staff scientists a more up-to-date, factual basis to assess the need to design measures that limit or avoid observed ecological or environmental problems. Such measures might be pursued through education, formulation and use pattern changes, or cooperative efforts with consultants and applicators. Yet, DPR's ability to move forward with such measures is often limited.

Accordingly, the basic role of efficacy data needs to be reconsidered. While regulators have the authority under FIFRA and state laws to require registrants to produce such data, they typically lack ways to meaningfully act on the information received. Products that just do not work are typically withdrawn by registrants and quickly discovered and shunned by farmers and pest control operators. The real value of efficacy data, if properly developed, would be as an input to the efforts of growers, crop protection specialists, and researchers working on the design and refinement of safer crop protection systems. It is regrettable but true that the laws, policies, and institutions shaping and governing pest control practices in California do not collectively provide for that outcome to occur, except in unusual circumstances. Yet it is that outcome *alone* that can accelerate progress toward safer crop protection systems.

NEW TERMS AND CONCEPTS TO HELP PRIORITIZE DPR ACTIONS

Several new and generally unfamiliar terms and concepts are used throughout the report. Their purpose is to provide regulators, at both the state and federal levels, with new tools to help set and act on priorities and to decide when certain regulatory actions should be expedited.

These new concepts are needed because regulation in the 1990s may become excessively bogged down by process and the sheer volume of work. Ways are needed to draw on available data, experience, and judgement to act decisively when the need arises to reduce risks associated with an existing product or when a new pesticide product might offer growers a safer control alternative. These terms also are needed to help provide a basis for shifting the focus of regulation from "one product at a time" regulation to advancing safer pest control *systems.*

Following definitions of new terms, key distinctions among them are described. As these terms are refined and applied, they will provide regulators a reasoned basis for actions and policies which have the potential, over time, to foster progress toward safer pest control systems.

A Caution It is important to acknowledge that several of these definitions are both controversial and difficult to translate into precise regulatory criteria. During meetings of the Advisory Committee for this study, these definitions were among the most contentious items discussed. Their importance reflects the prospect that these definitions could lay the foundation for major substantive changes in the focus of pesticide regulatory activities at both the state and federal levels, with major long-run consequences. Hence, the attention they have received is appropriate.

Safer **pesticide product** is a relative term. It is used to denote a pesticide product with one or more desirable physical, chemical, toxicological, biological, *or* ecological properties relative to other registered pesticide products or non-chemical pest control alternatives.

A *safe* pesticide product is an absolute term -- "absolute" relative to some distinct standard rather than in the sense of forevermore certainty. It refers to a pesticide product with desirable physical, chemical, toxicological, biological, *and* ecological properties that render it capable of accomplishing its intended impact on target pest species while having insignificant or no adverse impact on humans, the environment, or the ecology of plant-pest interactions.

In this context, "insignificant or no" means an exceptionally low probability of negative impacts: a finding that regulators would make based on data available on the product's inherent properties and what is known about its use in the field. If "safe pesticide product" were defined only by absolutes such as "zero risk," "no chance of posing risk," and/or "safe," then few if any products would fall under the definition.

[NOTE: A "safe" pesticide product is defined here comprehensively, taking into account chemical, toxicological, biological, and ecological properties and impacts. The definition could be applied alternatively to combinations of properties/impacts.

A pesticide product might be deemed "safe" in terms of prospective environmental and ecological impacts but fail to meet the criteria/standards applicable to human health effects. Such a product might be judged "safer" relative to other registered products but not "safe" in a comprehensive sense.]

A high risk pesticide product is a formulated product that is characterized by patterns of anticipated pesticide exposure requiring heightened caution to assure adequate margins of human and/or environmental safety. Alternatively, a high risk pesticide product may be one which is known, based on documented field experience, to exacerbate problems with target pests or nontarget organisms.

A high risk pesticide use pattern is a pest-crop-pesticide combination associated with patterns and levels of anticipated pesticide exposure requiring regulatory actions or heightened caution to assure adequate margins of human and/or environmental safety, or in which pesticide-induced pest problems have been documented.

A *safer* pest control system is a relative term that encompasses most integrated pest management and biocontrol systems. It refers to a system of pest management which, in contrast to pesticide-intensive control systems, successfully incorporates use of plant genetic, cultural, and biological control methods as a first line of defense.

A *safe* pest control system is an absolute term ("absolute" here is relative to some distinct standard, not a forevermore certainty). It refers to a system that successfully suppresses pests below damaging levels through a combination of the use of safe pesticide products and the use of plant genetic, cultural, and biological practices and tactics.

Distinctions Among Terms The terms "safer" and "safe" are sometimes used interchangeably, whether referring to a pesticide product, an active ingredient, or a pest control system. In using such terms in the context of regulatory reform, clear and precise definitions are essential, so that people can intelligently discuss what might happen as a result of a given policy proposal. Seemingly minor differences in definitions, or intended meaning, can have profound implications in the policy implementation phase.

The above definition of safer pesticide should ideally be applied to formulated end-use *products.* It is difficult, if not impossible, to make *relative* judgements regarding the safety of active ingredients because the conditions of their use make such an enormous difference in determining the relative safety of pesticide products. It is possible, but still difficult, to define standards of performance that might be used to designate what might be called a *generally* safe pesticide active ingredient.

Both "safer pesticide product" and "safe pesticide product" are terms that can play a useful role in devising new regulatory policies to pursue safer pest control systems. For example, regulators might speed up actions to grant new registrations to products that comprehensively meet the standards used to designate a safe pesticide product and otherwise exempt safe products from specified requirements and restrictions. They might also develop new rules and procedures to expand margins of safety when access to safer products would provide growers additional options.

One distinction between a safer pest control system and conventional systems is that a safer system -- because it is, by design, specific to conditions in a given field -- incorporates a combination of the use of safe pesticide products and non-chemical practices and tactics generally expected to manage pest populations so that, in most years, they do not reach damaging levels. Traditional pesticides and biochemicals can and will continue to play an integral role in many, though not all, safer pest control systems by providing growers the means to --

* Suppress pest populations when they are most vulnerable and when minimal adverse impacts will be felt on nontarget species

- Disrupt normal feeding, physiological development, or reproductive patterns of pest species

- Provide growers a method to save crops when, for whatever reason (unusual weather, pest migration into an area, resistance), previously effective pest management systems break down, allowing pests to reach or exceed damaging levels

Most conventional and IPM systems utilize nonchemical practices and tactics. But unlike safer systems, they also include pesticide applications as a routine, generally unavoidable component of the system, often because of the lack of proven alternatives. As new biorational pest control agents are registered and more is learned about how to use them to manage crop-pest interactions, growers will become less reliant on *routine* pesticide applications and, when pesticides must be used, more of them will be safe pesticide products. With steady progress in the science and art of pest management, the distinction between IPM as currently practiced and safe pest control systems will blur and may eventually disappear.

In the years ahead, further analysis will be needed to determine how to deal with the novel properties of emerging microbial and genetically engineered pesticide products in the context of the above definitions. Little is known now about how such products will fit into contemporary IPM systems, or how they might alter plant-pest interactions or soil microorganisms. Still, the basic concepts suggested above could be used in developing ways to evaluate the possible significance of such products in broadening the tools growers can choose from in working toward safer pest control systems.

CHAPTER III: STATE AND FEDERAL REGULATORY PATHS TO RISK REDUCTION

The capacity of DPR to assure safe pest control systems in California is constrained by the technologies and products the private sector believes are economically viable, as well as by which pesticide products survive EPA's review process. Pest pressure, which in agriculture is a function of cropping patterns and farm management decision making, is another critical factor.

In striving to assure access in California to safe, effective, and affordable pest control systems, DPR and EPA face several common challenges and needs. Despite progress made during the 1980s, both agencies continue to experience compelling needs for better, more complete data and improved risk assessment methods.

But better data and better science, in and of themselves, do not reduce pesticide risks. Taking advantage of major progress made in filling data gaps, regulatory scientists will be able in the 1990s to more accurately estimate California exposure and risk profiles: a key step in fashioning risk mitigation measures. DPR also will need to monitor continuously the effectiveness of risk mitigation measures in the real world, taking into account how people actually use and come into contact with pesticides in the home, through the environment, or on the job.

NEEDS AND POLICY DISPUTES IN COMMON

DPR and EPA have many needs in common, despite differences in their missions and responsibilities. For example, both must have data to characterize risk, both need improved systems and procedures for managing escalating workloads, and both seek the authority and capacity to act swiftly.

Furthermore, both DPR and EPA are engaged in the same ongoing policy disputes. On the one hand, when essential data to characterize a pesticide's toxicological potency and estimated exposure are available, both agencies know how to determine relative margins of safety and are in general agreement regarding how to prevent adverse health effects among different populations (depending on whether a person's exposure to the product is as a field worker or a consumer). However, even though DPR and EPA have the technical skills to conduct risk assessments, both agencies find themselves in treacherous waters when the political process provides unclear or conflicting guidance regarding precisely what the margin of safety must be to grant, retain, suspend, or cancel a California or federal pesticide product label. Setting acceptable margins of safety is a task that requires balancing fundamental values and goals: a job for politicians.

Many unresolved pesticide regulatory issues involve questions waiting for social consensus rather than scientific clarity. One such issue has to do with determining the relative priority and methods of preventing excessive exposure to certain pesticides among infants and children -- subpopulations that are more vulnerable because of their stage of development. More generally, society has yet to define "safe" in the context of pesticide risks, nor has it agreed on which benefits to whom count when "balancing" risks that are typically faced by others. Both risk and benefit measurement problems further complicate the balancing act regulators are called upon to perform. In the meantime, DPR and EPA make thousands of decisions. They need rules to live by.

At the federal level, legislation is needed to resolve fundamental issues involving acceptable levels of risk and whether risk standards should be solely health-based or should allow consideration of benefits -- and, if so, how benefits are to be defined and measured. Until a definitive consensus on risk standards applicable to pesticide regulation has been reached, every controversial decision made by DPR or EPA becomes a new opportunity for special interest groups to renew the debate over the proper standards to which regulators should be required to adhere. Approaching these fundamental issues on a case-by-case basis is both needlessly contentious and profoundly inefficient.

Recommendation #12: Publish Interim Guidelines for Pesticide Regulatory Decision Making

DPR and EPA cannot defer actions nor can they avoid unresolved policy issues while the California Legislature and U.S. Congress struggle on, trying to reach consensus on unresolved risk standard issues. Until the issues are settled in the political and policy process, both agencies need to advise the public of the bases upon which they intend to and do make regulatory decisions and take regulatory action.

In California, *we recommend* that DPR, in periodic published policy notices, make explicit its basis for judgements that specified risk mitigation measures are needed. *We further recommend* that such generic notices include the following, based on DPR's review of its own policies, procedures, decisions, and actions related to circumstances it commonly evaluates --

* Levels of acceptable risks, by defined population groups and environmental quality standards

. DPR's methods for quantifying such risks

- Basis for DPR's judgements that a given set of risk mitigation measures will reduce risk to acceptable levels

The information listed above in effect constitutes the rules for DPR's pesticide safety decisions. *We recommend* that, for each decision affecting a specific pesticide product, DPR provide a straightforward explanation of how it determined whether a given level of exposure might

cause risks higher than DPR considers acceptable. Such rules and explanations will not eliminate scientific uncertainty nor make the job of risk assessors any easier but, as a matter of policy, they will build into DPR's decision making a higher degree of transparency, consistency, and predictability. The benefits to the program of these virtues will outweigh the occasional costs arising from somewhat lessened flexibility for scientists to make judgement calls.

Recommendation #13: Invite Guidance on Key Regulatory Program Decision Rules

DPR's criteria, standards, or definitions (such as those used as the basis for establishing margins of safety for a new health effect or for determining "significance" in economic impact or "viability" of alternatives) deserve the benefit of periodic public review -- a process that will sometimes culminate in legislative action. An interactive communications process over these matters keeps registrants, growers, environmentalists, EPA, and others apprised of the decision rules governing DPR's program, including any changes in those rules.

We recommend that DPR initiate an internal process within Cal-EPA to establish coherency in criteria, standards, and definitions used by all departments, agencies, and offices within Cal-EPA on matters of policy and science. *We further recommend* that Cal-EPA then --

* Inform the public through workshops, hearings, and other methods of the criteria, standards, and definitions underlying its constituent agencies' regulatory decisions regarding margins of safety

- Request guidance from the public and interested parties regarding how stated criteria, standards, and definitions should be changed or clarified, including the process Cal-EPA should pursue in doing so, and which resources should be used

Over the next few years, DPR and Cal-EPA will have occasion to address several fundamental policy issues through this approach. *We recommend* that DPR and Cal-EPA follow a similar procedure with regard to the following issues emerging in pesticide regulation --

- Basis for dealing with uniquely sensitive population subgroups, including farmers who have become more sensitive through repeated exposures

- Criteria and standards for action to reduce the chances that pesticides will contaminate surface water or groundwater

- Criteria, standards, and definitions for a *safer* pesticide product and a *safer* pest control system

- DPR's responsibility and options to act when unusual circumstances give rise to true crises entailing major, immediate risks to public health or crop losses

We further recommend that DPR and Cal-EPA assist the Governor and Legislature in monitoring federal legislation for purposes of participating in the crafting of those provisions of federal law which will affect the role of states in pesticide regulation and alter the standards and regulations which DPR is required to enforce.

DATA GAPS

DPR and EPA have made significant progress in filling core toxicology data gaps. At the state level, the process mandated by California Food and Agricultural Code Article 14 (Birth Defect Prevention Act of 1984 [SB 950/Petris]) began in 1985 with the targeting of 200 active ingredients and a requirement that registrants submit the 10 core toxicology studies required by EPA. Of the initial 200 active ingredients, 178 had current registrations when the review period began. DPR needed a total of 1,780 core toxicology studies for these 178 active ingredients. By 1988, slightly more than half of the required studies (52.8 percent) had been submitted by registrants or were underway.

By May 1992, the percentage of requirements met by studies already submitted or underway had risen to 82.8 percent. Table III.1 summarizes the progress made between 1988 and 1992. Further information on the number of studies needed per active ingredient, along with the data used to calculate the percentages in Table III. 1, appears as Table 5.1 in Appendix 5.

The Pesticide Contamination Prevention Act (Article 15 of the Food and Agriculture Code, added by AB 2021/Connelly) added new data call-in requirements. The focus of Article 15 is to require DPR, on the basis of six new types of data, to assess the potential for a given pesticide product to leach into groundwater. In 1989, new legislation (AB 2161/Bronzan) required DPR to begin on July 1, 1990 to assess dietary risks from exposure to pesticide residues, focusing on acute effects and based on new insights made possible by review of the toxicology studies submitted pursuant to SB 950.

> *Med-Tox must feel like a termite on a redwood tree."*
>
> -- California Public Health Official

Taken together, state legislation in California has provided part of the national impetus to fill data gaps on pesticide safety, thereby improving the science base for regulation. While implementation of the legislation has strained DPR's resources -- especially in the Medical Toxicology Branch -- it also has stimulated the Department to streamline administrative procedures and to gain the scientific capability to conduct risk assessments independently.

Table III.1: Progress in Filling Core Toxicological Data Gaps for Priority Active Ingredients under SB 950: September 1988 to May 1992

	Percent of Active Ingredient Cases 10/88 : 5/92	
Status of Data Gaps		
All requirements met	7.8%	29.1%
Studies in hand, incomplete review	23.6%	27.8%
Commitment made to do all studies	21.3%	25.8%
Discussion ongoing regarding studies	24.1%	9.3%
No commitment to conduct studies	23.0%	7.9%
All requirements met, studies in hand, not all reviewed	31.5%	56.9%
All requirements met, studies in hand, commitment made	52.8%	82.8%
Discussion ongoing regarding required studies	24.1%	9.3%
No commitment to conduct studies	23.0%	7.9%
Discussion ongoing, no commitment	47.2%	17.2%
Total Number of Active Ingredient Cases	178	151
Number needing additional data	122	
(Percent)	(68.5%)	(43.0%)

SOURCE: Derived from data reported in Appendix 5, Table 5.1.

AUTHORITY AND CAPACITY TO ACT SWIFTLY

When a new study or a poisoning incident demonstrates that either a calculated or an actual margin of safety is inadequate, regulators need to act swiftly to reduce risks to the public. Both DPR and EPA have emergency suspension authority but use it rarely, because suspension is procedurally onerous and because the burden of proof is great and falls squarely on the regulatory agency.

DPR, whose emergency suspension authority turns on a finding of "immediate and substantial danger," has invoked this authority only five times. Two suspensions took effect in the late 1970s -- one eliminating home uses of the pesticide Vacor, the other banning all uses of DBCP. A third emergency suspension, effective June 25, 1987 involved uses of the insecticide cyhexatin. More recently, bentazon and cyclohexamide also were suspended.

EPA's emergency suspension authority, which requires a finding of "imminent hazard," has been invoked only three times -- suspending 2,4,5-T/Silvex in 1979, grain fumigation uses of EDB in 1984, and dinoseb in 1986. While emergency suspensions are rare, it is common for DPR and/or EPA to recognize the *clear need* for risk reduction, even though available data do not support an "immediate and substantial danger" or "imminent hazard" finding.

DPR has greater authority and capacity to act swiftly than EPA. If excessive risks are associated with particular crops, regions, formulations, or application methods, DPR can target its actions accordingly. When DPR recognizes the presence of unacceptable risks, the Director has a number of options, several of which can be exercised within a matter of hours. For example, DPR can --

* Suspend a registration or set of registrations statewide, effective immediately

- Require additional risk mitigation measures through emergency regulations

- Suspend use permits at the local level, temporarily halt applications, or impose special risk mitigation measures targeted to only where they are needed

A key distinction in federal suspension and cancellation processes (other than emergency suspensions) is that pesticides under consideration for these actions remain on the market and are legal to use in accordance with federal labels while EPA is conducting special reviews or pursuing suspension or cancellation actions. In contrast, the Director of DPR can suspend registrations, cancel permits, or otherwise act to reduce risks to acceptable levels *quickly* -- generally before the next applicable cropping season.

> *I can't tell you how many times we wish we had California's process to work within. Our process is much more convoluted."*
>
> -- EPA Official

The capacity to act swiftly, even in the absence of complete information, is an important component of DPR's regulatory authority. That authority, in combination with DPR's willingness to deploy it, occasionally has the effect of accelerating progress at the federal level in addressing problems which EPA might not otherwise deal with until later. A recent example is the significant changes in federal labels to

add new safety precautions for use of methyl bromide as a structural fumigant. These federal level changes are based on and were motivated by actions taken earlier by DPR.

Unlike EPA, DPR has shown a tendency to act first to reduce risks and ask questions later -- questions such as whether further steps are warranted or whether initial steps went too far. This strategy has proven reliable in the sense that DPR has generally found ways to incrementally reduce risks without canceling a pesticide's use.

FEDERAL APPROACHES TO RISK REDUCTION

When federal EPA receives new data indicating that a pesticide may pose greater risk than once thought acceptable, EPA first has to determine whether a "special review" should be triggered. If so, the agency begins what is often a long process leading to a final determination of how to balance risks and benefits. Almost always, a large volume of additional data is requested and must be developed by registrants and analyzed by EPA. Some special reviews have continued over a decade. Few reach closure in less than four years, other than those that are dropped when EPA is convinced its initial concern was unfounded.

In a few cases, new data triggering alarm provide strong enough support for an agency decision to proceed right to a suspension action. Such was the case with dinoseb following EPA's receipt of a new teratology study showing unacceptably narrow margins for women exposed to the pesticide in the field or in a food processing facility.

EPA's Mandate The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that EPA balance the risks and benefits of pesticide use. Its basic goal in granting a registration or reregistration is to avoid "unreasonable adverse effects in man (sic) or the environment." 1988 FIFRA amendments mandated an accelerated reregistration process, which is now underway. Reregistration fees of some $150,000 per active ingredient plus the high cost of satisfying new data requirements have led companies to cancel thousands of pesticide product labels voluntarily (see Table III.2). While EPA's official forecast is that the reregistration process will be completed by 2005, senior program officials admit this date is unrealistic because of the delays ensuing from requests for additional data.

Table III.2: Impact of Federal Reregistration on the Number of Available Pesticide Products and Active Ingredients

	1989	1990	1991	1992
Registered Products	45,000	25,200	20,700	19,200
Number of Products Canceled	19,800	4,500	1,500	200
Active Ingredients	1,153[2]	787[3]	704[3]	678[2]
Percent Change:				
1989 **to 1992** Registered Products				-57.3%
Active Ingredients				-41.2%

NOTES:
[1] ThroughMay 1992
[2] Taken from EPA data
[3] The numbers of active ingredients shown for 1990 and 1991 are estimates, based on an average of 54 products per active ingredient canceled from 1989 through 1992 (25,800 products canceled divided by 475 active ingredients lost)
SOURCE: Data provided by the Special Review and Reregistration Division, Office of Pesticide Programs, U.S. EPA, 1992

Nationwide Decisions EPA makes federal reregistration decisions, and accompanying label changes, on the basis of "average" national conditions. As a result, EPA's decisions often do not address risk mitigation needs unique to California (or other states).

The federal reregistration process has not yet reached final decisions on major food use pesticides. The Registration Eligibility Documents (REDs) completed thus far are on relatively minor pesticides -- "numerical REDs...the chickadees of the reregistration pond," in the words of one EPA official. The RED on an active ingredient will lay out the requirements for risk mitigation measures on all uses, as well as those applicable to individual crops. This document also explains the label changes which must be made for various products containing the active ingredient in

question. Because this state's agricultural sector is so big and so diverse, however, EPA is often unable to specify the risk reduction measures necessary *within* California on a single statewide label.

A negative conclusion to EPA's reregistration process for an active ingredient, or a specific set of crop uses, is a finding of "ineligible for reregistration." On its own, this finding has no effect. In order for EPA to force an "ineligible for reregistration" pesticide product off the market, or to reduce risks associated with its use through label changes, EPA must initiate and go through the special review process unless a negotiated settlement can be reached that reduces risks enough to satisfy EPA's concerns. As noted earlier, in the meantime, the product remains on the market.

EPA expects that, normally, it will take about one year from the publication of a RED for EPA's Registration Division to review and approve revised labels submitted by registrants. If EPA is to complete some 400 REDS by the year 2005, it will need to finish an average of at least 30 per year-- a monumental task. Even getting all the List A chemicals reviewed by 2005 would be a major accomplishment. At the peak of addressing major food use chemicals in the mid to late 1990s, EPA may issue annually 15 or more REDs on major chemicals, each encompassing several dozen (some encompassing more than a hundred) individual pesticide products. For each of these products, label amendments consistent with the RED will have to be developed by the registrants and approved by EPA. Once these revised labels are reviewed and approved by EPA, registrants will seek DPR's approval of the same label amendments on a product-by-product basis.

DPR's RESPONSE TO EPA's REREGISTRATION DECISIONS

In recent years, DPR has raised questions and sought changes in a significant portion of the label amendments approved by EPA. DPR most frequently questions compliance of proposed labels with EPA's own regulations and data requirements and sometimes poses requests for additional data needed in California to assess whether a label's applicator and farmworker risk mitigation measures are adequate. EPA addresses such issues generically through the reregistration process rather than through review of a registrant's request to amend a specific product label. But in California, every label amendment that might alter the risk associated with use of a pesticide product is reviewed comprehensively, with special attention to worker exposure or water quality risks (if there is *any* reason to think such risks may be excessive).

Only in a relatively few cases has DPR questioned EPA's basic risk-benefit evaluations. However, it is all but inevitable that California's more extensive data base will lead DPR in the future to go beyond EPA's risk assessments more often and to decide in many instances that additional risk mitigation measures are necessary statewide, or in parts of the state, with respect to worker safety, water quality, risks to pollinating bees, or other concerns.

Recommendation #14: Blend California's Data Requirements to the Fullest Extent Possible with Data Requirements Imposed by EPA

> A "use pattern" is defined by the combination of how, where, how often, and under which restrictions and safety precautions a pesticide is approved for application on a given crop or field.

Some combination of federally required and state-specific data will be necessary to enable state level regulatory agencies to perform risk assessments relevant to state-specific agricultural conditions and use patterns. DPR has set the standard for this activity at the state level throughout the nation and, in so doing, has learned the value of cooperation with EPA. On this basis, we recommend that DPR --

* Continue to rely on EPA's data requirements and testing protocols to the fullest extent possible

- Play an active role in shaping EPA's future data requirements, especially in areas of special concern in California (such as farmworker exposure and interactions of pesticides with irrigation management practices)

- Develop mechanisms to prioritize the requests for California-only data, targeting initially those pesticide use patterns that raise the most significant concerns

- Routinely share with EPA the results of any California-only studies which suggest the need for risk mitigation measures which may be warranted outside of California and can best be accommodated through revision of federal labels

MANAGING RISK CONCERNS IN CALIFORNIA

A major issue looms on the horizon: namely, will label changes approved by EPA address DPR's risk mitigation concerns? EPA does not now seek input from the states as it completes REDs, nor does it plan to, partly because there is no mechanism for doing so and partly because Congress is pressuring EPA to keep reregistration on schedule. Therefore, EPA's risk mitigation decisions will be based on risk-benefit standards in FIFRA, drawing upon the data which registrants have filed to satisfy EPA's requirements. Situations unique to California (or other states) are unlikely to factor prominently in EPA's decision making. In short, the direction of flow in the reregistration process is from EPA to the states; states will not have an opportunity to affect the outcome.

Once EPA has made a reregistration decision, states will have little choice but to accept the outcome. Federal law prohibits DPR (or any state regulatory agency) from making changes in federal labels in response to state statutory and/or regulatory obligations. As a practical matter, EPA cannot accommodate on a single federal label the diversity of pests, cropping systems, and technologies found across American agriculture which, taken together, determine the nature and

magnitude of pesticide risks that actually arise in a given state. At the same time, following the enormous investment in new data and improved risk assessments that form the core of EPA's reregistration decisions, states should not settle -- and many won't -- for essentially generic federal label amendments that in many cases will be inadequate or inappropriate because of unique conditions under which particular pesticides are used in a particular state.

> *"I don't give a damn what the rest of the country is doing. What's important to me is articulating the right vision for California."*
>
> -- California Public Health Official

The state-federal partnership which the country relies on to accomplish pesticide regulation may be in jeopardy unless better ways are found for states and EPA to share in the process of identifying excessively risky use patterns, crafting risk mitigation measures, and incorporating this information in federal labels. The existing federally-dominated process for crafting risk reduction could easily buckle under the strain of the number and significance of actions that will need to be taken, both at the federal level and in individual states. Risk reduction measures which are acceptable and make sense in California may differ from those needed and acceptable in Florida, Oregon, Iowa, or New Jersey.

The simplest, most direct solution to this fundamental problem would be for Congress to add a new provision to FIFRA allowing states to add supplemental, state-specific labels onto pesticide containers, next to federally-approved labels. EPA would need to review state-specific label supplements to assure consistency with provisions on federal labels: a task less resource-intensive for EPA than trying to stay abreast of unique exposure and risk scenarios in 50 states.

This would be a significant change in the nation's pesticide policy and would provide the foundation for a new, more balanced state and federal partnership. It also would markedly enhance EPA's ability to grant regional tolerances and geographically restricted registrations, representing perhaps the best hope in dealing with minor crop issues. Registrants, however, vehemently oppose giving states the right to add supplemental labelling, citing the cost of dealing with "50 little EPA's."

DPR's RISK MITIGATION OPTIONS

DPR has a number of options when responding to findings of unacceptable risk. Under current law, DPR may --

* Deny a new label or cancel or suspend an existing registration

- Suspend or deny a label, but issue a Section 24(c) (Special Local Need) label that includes the desired changes in use patterns and risk mitigation measures (an option just recently made possible by a change in EPA policy)

- Impose California-only risk mitigation measures through regulations or permitting requirements

- Encourage registrants to seek and obtain changes in federal labels which might apply nationwide, or to California only

In general, DPR prefers that registrants choose to pursue the last option and sees the first option -- denying a label or suspending a product -- as too radical a step for a pesticide that has been contributing, or could contribute, to safe and effective pest control systems even though it *may* pose unacceptable risks if used in accordance with the maximum rates specified on the label in certain sensitive ecosystems or high-exposure situations in California. Moreover, state law requires DPR to consider and pursue risk mitigation measures *before* turning to the option of suspension.

The second option -- denying a Section 3 label, but issuing a 24(c) -- will be a viable alternative only in a few cases, since federal law and EPA regulations prohibit approval of a §24(c) label if an effective, registered alternative is available. In addition, EPA has raised the fee for securing a §24(c) label to $1,200 -- a sum beyond the routine reach of most states, let alone counties (which, in California, are most often the applicants for 24(c)s).

The third option -- imposing risk mitigation measures through regulation or permit requirements -- is the functional equivalent of recalibrating the outcome of the federal reregistration process by taking California-only regulatory action. While viable in some instances, it would impose significant costs on both registrants and DPR. Having invested millions of dollars and years of effort to satisfy EPA's concerns prior to the final issuance of a RED, registrants could be expected to lack enthusiasm for starting the process anew with DPR. Augmenting federal labels through local regulations and permits also would impose new burdens on DPR and county agricultural commissioner staffs, presumably without an increase in resources.

The last and fourth option -- encouraging registrants to seek changes in EPA labels -- is generally preferred by DPR, even though DPR is prohibited by federal law from requiring changes in federal labels. Incorporating risk reduction measures on the federal label limits the chance for confusion among California growers who know that pesticide labels have to be followed but may be unaware of other restrictions imposed through DPR regulations. Furthermore, incorporating risk mitigation measures onto federal labels assures that California producers have access to the same crop protection tools available elsewhere -- and also assures larger margins of safety for applicators, farmworkers, and citizens in other states.

However, registrants resist the path of seeking changes in EPA labels, because they fear setting off a process with unpredictable outcomes. EPA sometimes acts quickly on proposed label amendments but, in other cases, the request for a label amendment has set in motion a broader reassessment than registrants sought or thought would be necessary to approve the requested

changes. Even in the best case scenario -- quick approval by EPA -- there is no guarantee that EPA-approved label amendments will in fact satisfy DPR after it has reviewed the data.

Registrants have learned that DPR, like EPA, can also be unpredictable in assessing the adequacy of label amendments. Under current policies, DPR generally does not tell a registrant which changes in a federal label would satisfy its concerns; to do so would imply a guarantee of state concurrence. What happens is that registrants, DPR, and EPA play a "cat and mouse" game: registrants try to pin down DPR and EPA on what their concerns are and what will satisfy them, but the regulated community is clearly vulnerable to the uncertain outcomes of EPA's decision making process on approval of label changes and DPR's process to decide whether to accept those changes.

Recommendation #15: Systematically Focus Scientific Staff on Efforts to Reduce Risks from "High Priority" Pesticides Registered for Use within "High Risk Use Patterns"

DPR now identifies "high priority" pesticides through the Adverse Effects Advisory Panel, which reviews SB 950 data. This is part of an evolving methodology to more efficiently deploy scientific and regulatory resources in response to Cal-EPA's overall goal of targeting resources on the greatest risks. The current methodology consists of scheduling reviews and directing risk assessment resources preferentially toward "high priority" products and, in other DPR branches that assess pest management needs and practices at the field level, focusing on "high risk use patterns," as in the 1980s in the wake of fish kills following herbicide use in rice production.

A "high pesticide use pattern" is a crop-pest-pesticide combination associated with levels of pesticide exposure to humans or nontarget species that result in narrow margins of safety or environmental loadings that pose long-term ecological or health risks.

The Adverse Effects Advisory Panel (AEAP) draws appropriately upon both DPR scientists and those in Cal-EPA's Office of Environmental Health Hazards Assessment (OEHHA) in placing pesticide active ingredients or products into one of three priority groups for risk assessment. But the high priority group already contains nearly 50 active ingredients -- enough to keep DPR staff scientists busy for at least a decade at current staffing levels. Moreover, EPA and DPR experience has shown over and over that pesticide risks should be assessed and mitigated across all products registered for use on a given crop/type-of-pest combination (for example, insecticides on tomatoes) to avoid merely transferring risk from one restricted or suspended product to others remaining on the market.

However, DPR cannot set health-based priorities on the basis of only chronic data. The mission and charge of the AEAP is limited to reviewing core toxicology data generated under SB 950. If AEAP is to play an integral role in setting DPR priorities, its mission needs to be expanded to encompass acute and other types of health effects, and it will need greater depth and breadth of scientific expertise as well as additional resources.

Accordingly, *we recommend* that DPR develop a second mechanism to help set and pursue priorities for risk assessment and risk mitigation. Through a new mechanism, DPR should formally identify high risk use patterns, drawing initially on staff expertise and an external advisory panel. Then, DPR should target risk assessment resources to active ingredients and products from AEAP's high priority list that are used within high risk use patterns. Likewise, DPR's field-based branches should also target their efforts on newly designated "high risk" use patterns, so that over a two to three year period, DPR comprehensively develops insights about pest control challenges and risks associated with a given crop-pest combination.

A first step in this process is for DPR to identify an initial six to 12 high risk use patterns. DPR should also define the criteria for selecting use patterns to scrutinize in the future and for moving use patterns onto and off the list in a routine annual cycle. Furthermore, DPR should explore adoption of new policies and activities it could direct toward reducing risks and expanding control options in high risk use patterns. *We recommend* that DPR include among the options studied --

- For applications seeking a label for use of a new product within a high risk use pattern:
  - -- Request registrants, growers, and pest control advisors to provide information on recommended pest management and risk mitigation measures that will help DPR assure adequate margins of safety for *all* pesticides that might be needed to keep crop losses below economic thresholds
  - -- Through fast-tracking mechanisms, accelerate the completion of registration actions when data and experience with the same or similar chemicals suggest that the new pesticides will provide growers or users a substantially greater margin of safety
  - -- Grant conditional registrations while additional data are being generated and reviewed *provided* existing data support a conclusion that the new product represents a safer alternative
- Make more frequent use of quantitative limits on the total pounds of a pesticide that may be used in a given area or in a particular setting or location or on a given crop (preferably through limitations on the number of applications, timing of applications, and/or the total volume of pesticides used in addressing a particular control need)
- As is currently the case, target the field-based efforts of the Environmental Monitoring and Pest Management Branch to high risk use patterns

- Impose interim, single season, geographically limited, or otherwise provisional risk reduction actions, subject to modification as new information becomes available (as currently done in certain instances)

- In *exceptionally* high risk use patterns, such as the worrisome situation looming on the horizon involving soil fumigation:
  - Encourage changes in private sector research and development investment patterns

  - Invite registrants of previously canceled or suspended products to assess whether modern formulation, handling, and application equipment can be used to restore adequate margins of safety

  - Ask EPA to assess opportunities to provide growers with safer alternatives and to pursue options that emerge through collaborative efforts with USDA, CDFA, or the private sector

CALIFORNIA'S ENFORCEMENT CAPABILITY

More than 400 full-time equivalent staff devoted to enforcement of pesticide regulation are employed by county agricultural commissioner offices and DPR -- far more than in any other state. Most states, including several major agricultural states, have fewer than 10 people carrying out pesticide enforcement activities.

Its enforcement capability has given DPR considerable confidence in risk mitigation measures which are far more elaborate than those attempted elsewhere. Remarkably, DPR and county agricultural commissioners have the capacity to -- and occasionally do -- develop and enforce pesticide risk reduction plans specific to the level of a single field. Some risk reduction requirements apply only in certain counties, or on certain soil types, or in conjunction with particular types of irrigation systems or application technologies.

Despite its virtues, California's commitment to field level enforcement is seen as a double-edged sword both within and outside the state. California's enforcement capabilities, coupled with DPR's ability to carry out its own risk assessments, can force EPA to deal with a problem pesticide sooner than it had planned. Thus, California's enforcement capabilities can place EPA in a difficult position when the federal agency is considering nationwide risk mitigation actions on a given pesticide product label.

For example, EPA may be convinced that in California a certain high risk pesticide not only can but *will* be used under circumstances specified by EPA in which risks have been calculated not to exceed benefits. But EPA may wonder whether other states' enforcement capability will be adequate

to assure compliance with the specified risk mitigation measures. In this situation, EPA must decide whether to --

- Allow the use nationwide, expecting that risks are likely to exceed benefits when the pesticide is used outside California;

- Cancel the use, thereby denying access in California to a pesticide product which the state has developed the capacity to use safely; or

- Allow use in California under EPA's existing policy which allows the agency to establish regional tolerances and registrations.

The effectiveness of California's enforcement program is double-edged *within* California because it often translates into higher costs for California farmers. Sometimes these costs are hard to justify -- such as when EPA-approved nationwide labels call for a method of application or use of safety equipment that makes little sense under soil, climatic, or irrigation conditions unique to California. Under state and federal law, DPR has no choice but to enforce federal label restrictions -- even those that would seem not to apply because of differences in California production systems. In this sense, California's commitment to enforcement is a disadvantage relative to other states where such attention to detail is not possible.

Because of the diversity of California agriculture, many unique pest control challenges arise, involving just a few thousand, or even a few dozen, acres of high-value crops. Often pesticide use in these crops has a high potential for worker exposure to whatever extent the crops require pruning, weeding, watering, and other tending by field workers. Recognizing this prospect, DPR has devoted significant resources over several years to understanding how pesticides can be handled and used safely in the field. The Department's enforcement program is partly focused on implementation of these safety precautions.

Recommendation #16: Coordinate Design and Enforcement of Risk Mitigation with EPA

We recommend that the Governor and Legislature work with the President and Congress to ensure that federal pesticide law and policy are designed to capitalize on the investment California has made in pesticide enforcement. When California, or any other state, has developed a way to use a pesticide safely and EPA concurs that margins of safety can be assured through solid enforcement at the state level, **we** *recommend* that EPA should be asked to --

* Incorporate the affected state's required risk reduction measures on federal labels, in lieu of cancellation, unless EPA feels even stricter measures are needed in other regions

- Grant §24(c) labels to the state or a third-party registrant, waiving the $1,200 registration fee, even when other alternative products are registered

REGULATION AS PART OF THE PROBLEM RATHER THAN THE SOLUTION

Regulators work their will primarily by controlling the *number* of pesticides in the tool kit. When the tool kit was amply stocked and growing steadily, the loss of a "bad actor" rarely caused a problem. But the smaller the tool kit becomes, the greater the chance that losing more registered pesticides will set off unintended and undesirable consequences. The example of soil fumigants is illustrative.

California's Impending Soil Fumigation Dilemma Three soil fumigants in California accounted for most of the 33 million pounds of use in 1990, or about 35 percent of annual agricultural pesticide use (when sulfur, petroleum distillates, and other mineral or oil-based materials are excluded from the total [see Table III.3]). In the 1970s, six major registered soil fumigants were used on about the same acreage.

Both of the currently registered major soil fumigant products -- methyl bromide and metam sodium -- are candidates for designation as high risk pesticides and may themselves soon be the targets of regulatory action. The four major soil fumigant products lost over the last 12 years are described in Table III.4.

For many of California's major fruit and vegetable crops, methyl bromide is the product of choice. Although more expensive and less effective in many crops than either Telone or EDB, methyl bromide achieves varying levels of control of severe soil-borne insect, weed, and disease problems that plague crops in the absence of fumigation, unless a variety of typically costly cultural practices are employed.

Methyl bromide is under current regulatory pressure on two fronts. First, DPR and EPA scientists have grown concerned about its toxicity. Second, it is one of several chemicals of concern as a causative agent of thinning the ozone layer. In fact, an international agreement reached in 1987 (the Montreal Accords) is likely to lead to a phase-out of methyl bromide use in U.S. agriculture by or about the year 2000, because methyl bromide is over 60 percent as efficient as chlorofluoro-carbons in thinning the ozone layer.

Table III.3: 1990 Use of Soil Fumigants in California

	Pounds	% of All	% of All Minus Mineral or Oil-Based
Agricultural Pesticides	181,899,000	100.0%	N.A.
Mineral or Oil Based			
Sulphur	55,756,000	31.0%	
Petroleum Distillates	26,151,500	14.0%	
Copper Sulfate	2,593,357	1.4%	
Other* *	1.020.146	0.5%	
Total	85,521,003	47.0%	
Soil Fumigants			
Methyl Bromide	20,058,273	11.0%	21.0%
Metam-Sodium	5,934,082	3.3%	6.2%
Telone	5,183,793	2.8%	5.4%
Chloropicrin	2.248.653	1.2%	2.3%
Total	33,424,801	18.0%	35.0%

** "Other" includes Calcium Hydroxide, Calcium Hypochlorite, Calcium Chloride, Calcium Carbonate, Chlorine, Bt, ethyl alcohol, and soap.

SOURCE: 1990 Pesticide Use Report, DPR

Cancellation of methyl bromide would leave metam-sodium (most common trade name, Vapam) as the *principal* soil fumigant available for use in California' unless DPR reinstates Telone permits. Metam-sodium is not without its own safety and environmental drawbacks. Its toxicological profile, while not fully characterized because of data gaps, is worrisome.

Metam-sodium is also an environmental concern because of its tendency to be highly mobile laterally in soil. Several fish kills have resulted from the presence of Vapam in irrigation tail-water as it reaches streams and rivers. County agricultural commissioners have had to evacuate some residential areas and a few schools and parks because of excessive levels of Vapam in the air.

Table III.4: Regulatory History of Soil Fumigants

Fumigant	Nature of Action	Basis for Action	Year
DBCP	Canceled	Oncogenicity	1977 CA
		Mutagenicity	1979 EPA
		Reproductive Effects	
		Groundwater	
EDB	Canceled	Oncogenicity	1982 CA
		Mutagenicity	1985 EPA
		Reproductive Effects	
1,2-D	Suspended above 0.5%	Groundwater	1985 CA
Telone	Permit revoked	Oncogenicity	1990 CA
Methyl Bromide	Under Review	Developmental tox	1991 CA
		Neurotoxicity	1991 EPA
Metam-Sodium	Reevaluation	Hazard identification; labeling	1991 CA

SOURCES: EPA Status of Pesticides in Reregistration and Special Review, "The Rainbow Report," 1992; EPA Suspended, Canceled and Restricted Pesticides, 1990; DPR Registration Status Files.

Recommendation #17: Reassess Soil Fumigation Alternatives Based on Relative Risk

Technology and common field fumigation practices have changed dramatically in recent years, markedly reducing applicator and worker exposure levels and off-site damage potential. If DPR were to reevaluate the exposure and risks associated with all six soil fumigants that were on the market in the late 1970s -- assuming that each were now formulated, handled, mixed, and applied with state-of-the-art equipment -- a different picture of relative risks and benefits might emerge. Indeed, a previously banned or suspended product might offer the prospect of the largest margin of safety -- provided it is manufactured, handled, and applied with contemporary safety precautions.

For many pesticide use patterns in addition to soil fumigation, a combination of factors -- some caused by agricultural practice, others by nature -- will heighten the need for reevaluation of

"The multiple ways in which fumigants destroy the environment and threaten public health convince me that fumigation should not be allowed as a general policy, period. I am not saying everyone shouldfarm organically. But I think every farmer should have a soil that is alive, and that farms where every living thing in the soil is killed every year cannot be sustainable. These farms rob California of its future. '

-- Technical Director, organization developing sustainable options for growers

past decisions and existing policies. Situations may arise with increasing frequency when EPA and/or DPR will need the authority to invoke special rules and procedures to expand pest control options when such actions are needed to achieve overall risk reduction. Indeed, DPR may need to take such an approach in the near future to deal with the soil fumigant situation in California. Rather than wait for the next shoe to drop, *we recommend* that DPR draw upon existing, relatively accessible information to --

* Assess and compare the *risks per-acre-treated* for currently registered soil fumigants with risks for EDB, Telone, and 1,2-D in major California crops (that is, projected risks based on available data arising from one acre of a given crop fumigated with each of the alternative products)

- Explore options to reduce risk through cultural, genetic, and biological practices and to let these practices assume a larger share of the control burden (the University of California has recently published a report that can serve as a point of departure)

- Estimate margins of safety under the assumption that all practical risk mitigation technologies (formulation, application equipment) and safety precautions are fully adhered to

- Determine the lowest overall risks that appear technically feasible if the most desirable combination of the six soil fumigants once used in the 1970s were available today

- Assess how regulation and enforcement activities might encourage progress toward safer soil fumigant options and practices if the potential for risk reduction appears large enough to warrant further analysis

Recommendation #18: Institutionalize Assessment of High Risk Use Pattern Control Options – Past, Present, and Future

The process for assessment of soil fumigation alternatives recommended above would provide DPR with important insights into how to approach other high risk use patterns. *We recommend* that DPR institutionalize this process, setting the stage for increasing the number of high risk pesticide use patterns that DPR can take on in a given year. We *recommend* that DPR expand its ongoing but modestly funded effort to --

- Draw upon expertise in the grower community, CDFA, USDA, academia, registrants, and crop consultants to identify high risk use patterns and compile inventories and assessments (extent, effectiveness, cost) of control practices currently used

- Seek innovative ways to expand public-private sector cooperation in funding and carrying out targeted field research on the impact of pesticides on integrated pest management systems

- At the state level, consult with CDFA, the University of California system, and state colleges -- and EPA and USDA at the national level -- regarding how safer pest control options might best be expanded, especially in high risk use patterns

CHANGES NEEDED AT THE FEDERAL LEVEL

As the reregistration process unfolds, risk reduction will and should be sought principally through changes in federal labels, including cancellations (both forced and voluntary). Registrants will understandably grow weary of staggering through the EPA process only to be caught up anew in another reassessment of risks, calls for additional data, and suggestions for further label changes at the state level. To simplify the process, we suggest that EPA establish routines and systems for exchange of monitoring data and risk assessments from the states -- before EPA completes its own risk assessment/risk management decisions.

Relatively few states have extensive data gathering and analytical efforts underway. Even in California, the data that would be new to EPA would be relatively limited, except in DPR's areas of special focus and concern -- such as farmworker and applicator exposure or irrigation management strategies for keeping pesticides below adverse effect levels in surface water or groundwater. Clearly, such data would also be of interest to EPA and may well increase the chances that label amendments approved by EPA will meet the state's needs.

Over the next 10 years, perhaps longer, regulators will often conclude that federal label amendments do not and cannot fully or adequately address risks unique to California or other states. In such instances, we suggest that EPA consider the following two options for opening viable paths to shift greater responsibility -- and *capability* -- to the states in designing and enforcing risk mitigation measures:

- Extend EPA's national groundwater protection strategy to other risk concerns

- Modify the §24(c) process to make it easier and cheaper for states to obtain Special Local Need labels

CHAPTER IV: MANAGING FOR EFFICIENCY

Pesticides interact with the natural environment in complex ways. An accurate risk assessment requires a broad array of data that must be combined with models or other methods designed to translate field measured levels of residues into estimates of human or environmental risks. Pesticide regulators charged with making judgements regarding a given product's safety have been plagued for years by gaps in knowledge and thus forced to decide between inaction and action based on limited data and understanding. Either way, regulators are shooting in the dark.

Often, more knowledge about pesticides serves simply to refine the next round of questions. The public and politicians expect regulators to be certain that registered pesticide products cause no harm, despite data gaps and scientific uncertainties. The U.S. Congress and California Legislature and U.S. EPA and DPR have diligently pursued ever more refined product testing requirements and data analysis strategies in order to reduce uncertainty about pesticide product safety.

There seems no end in sight to new data and risk assessment challenges, despite the fact that the system is already overwhelmed with data. Other problems both for regulators and registrants arise from the costs of generating, interpreting, and acting upon all the data now required to obtain and defend a pesticide registration.

THE COSTLINESS OF COMPLIANCE

The cost of complying with EPA plus DPR pesticide regulatory requirements exceeds the earning capacity of certain products, especially those registered for use principally on minor use crops. Risk-driven regulatory actions by EPA since the agency was formed in 1971 have led to the complete or partial suspension or cancellation of 45 active ingredients: seven chlorinated hydrocarbon active ingredients suspended before the special review process was initiated and 38 since the Rebuttable Presumption Against Registration (RPAR) and special review processes were initiated. Another 30 active ingredients have been voluntarily cancelled as a result of the special review process. Regulatory action has, therefore, led to significant reduction in the use of 75 active ingredients over 20 years, or just under four per year.

In contrast, registrants have voluntarily canceled all uses of over 475 active ingredients *since 1988* when passage of the FIFRA amendments accelerated reregistration and imposed a $150,000 reregistration fee. EPA analysts have determined that about 75 percent of the voluntarily canceled products were "paper registrations" -- that is, registrations for which no products had been manufactured in three years. The balance are registrations which registrants abandoned because of some combination of concern about risk and the cost of regulatory compliance.

Taking paper registrations into account, the cost and perceived difficulty of obtaining reregistration has led to the cancellation of all products containing some 120 active ingredients since 1988 -- still far greater than the number driven off the market by risk-driven regulatory actions over two decades. This recent shrinkage in the pesticide tool kit could disproportionately affect California because of the diversity of the pest control challenges faced by producers of "minor use" crops -- mostly high value fruits and vegetables grown on limited acreage. Minor use crops such as grapes *($1.5 billion* in annual sales, see Appendix 3), nursery products, flowers, lettuce, tomatoes, and almonds, are major sources of income, jobs, and tax revenue in many parts of the state.

SETTING AND ACTING ON PRIORITIES

DPR lacks adequate mechanisms to focus its efforts on high risk pesticides and use patterns. In part, DPR's seeming inflexibility is a result of having little room within its program to do anything other than what absolutely has to be done. Particularly in its Medical Toxicology Branch, DPR scientists are overwhelmed. They are struggling to implement a number of specific legislative mandates, each with tight and specific timetables, while also trying to carry out risk assessments on over 45 high priority, already registered active ingredients -- in addition to most new active ingredients.

Certain internal DPR policies and external "shocks" also make it difficult for managers to target program efforts to where DPR and Cal-EPA scientists feel margins of safety are either too narrow or inadequately characterized. Such shocks include more applications for new active ingredients than expected; an accidental pesticide spill or poisoning incident; or, immediate demands to decide what must be done to deal with a particular high risk pesticide or use pattern that for some reason gains widespread attention in the media.

Identifying High Risk Pesticides and Use Patterns As discussed in Chapter III, DPR needs to incorporate into its priority setting mechanisms an annual listing of high risk pesticide use patterns. The purpose of this list is to help provide structure across DPR branches in focusing on a particular set of products used within high risk use patterns, so that risk mitigation measures can be shaped comprehensively across the use pattern, reducing the chances that regulation will just shift risk from one restricted product to another registered alternative. DPR's overall goal should be to select for intensive review the optimal number of high risk pesticide products and associated active ingredients that it can deal with through the risk assessment and risk mitigation process over the next 12-24 months.

The purpose of expanding and formalizing DPR's priority-setting mechanisms is to help DPR retain a greater degree of control over where it invests its regulatory resources. Recall that one goal of Cal-EPA is to focus on the worst problems first. This can be achieved only through systematic deployment of existing resources. Remember too that the federal reregistration and special review processes are progressing along on schedules set by myriad factors far removed from relative risks

in California. DPR's workload, and the use patterns that get attention in any given year, will be driven by a combination of factors that include DPR's own evaluation of risks, the outcome of EPA actions, changes in law, or unexpected episodes that bring pesticide risks to public attention.

Hazard: Strength of a chemical's intrinsic toxicity; its potency or capacity to cause harm

Risk: Probability that harm will arise from a chemical's intrinsic toxicity, given how and where the chemical is used within a specific use pattern

DPR can neither change nor control many of the factors shaping its workload, but it can alter its response to them. The majority of pesticides and use patterns pose modest risk when label instructions are followed and caution is exercised. A few pesticides and use patterns, and a few geographic locations and soil types, account for the lion's share of actual harm from pesticide use in California, indeed around the nation. The sooner DPR develops mechanisms to remain focused on these high risk products, use patterns, and locations, the sooner the public, and everyone involved in agriculture, will reap the benefits of the hundreds of millions of dollars spent by DPR, EPA, and registrants on new data and more complex regulations.

High Risk Pesticide Product:
A formulated pesticide product that is characterized by patterns of exposure resulting in excessively narrow margins of safety, or which has been found to heighten the need for other pesticides posing unacceptable risks to people or the environment.

High Risk Pesticide Products In any given year, DPR is able to deploy about one-third of its scientific resources to in-depth risk assessment and risk mitigation efforts on high priority pesticide products about which it has concerns. Its remaining resources have to be devoted to reviewing and acting upon registration applications, including applications for new active ingredients. Note that the definition refers to high risk pesticide *products*, not high risk *active ingredients.* This distinction is important. The safety of a pesticide is determined by its toxicity in combination with expected exposure levels. While nearly all toxicity data refer to the properties of active ingredients alone, a pesticide product's formulation (the inert ingredients it contains) and use pattern (where and how it is applied) determine actual levels of exposure and, hence, risk. For this reason, it is difficult to designate an active ingredient as inherently either high risk *or* safer, based only on its chemical and toxicological properties. Exposure must be taken into account because of its great variation and, thus, its potential to heighten risk.

A New Method to Achieve Incremental Risk Reduction The nature of EPA's reregistration process -- a multi-year process of data collection, analysis, and finally a comprehensive decision -- leaves little room for incremental progress in reducing risks. Since pesticide product labels have to be approved by EPA before being submitted to DPR, the label amendment process affords DPR limited options to reduce risks incrementally. The federal-state partnership in pesticide risk

management might be termed a "red light/green light" process. The light is "red" -- holding back risk mitigation measures -- during the several years it takes EPA to require registrants to develop, and EPA to analyze, data. The light is "green" only for a short period when EPA finally feels it has enough information to act.

Creative steps need to be explored to widen the risk mitigation window of opportunity, since many small increments of risk reduction spread across more registered products can add up to far more public health protection than that achieved by the issuance of a few cancellation orders per year or completion of several reregistration reviews. An incremental approach would also help farmers, who generally prefer making changes gradually and who worry about their ability to control pests if draconian regulatory measures are imposed in a time frame that leaves little time to respond and adapt.

One new policy EPA and DPR might consider is to automatically approve on an "interim" basis -- pending in-depth review if considered necessary and when resources allow -- any proposed label amendment that includes a significant reduction in application rates (say, more than 30 percent and/or safer methods of application). This policy provides incentives: regulators promise a quicker and smoother path through the regulatory process for those applicants willing to propose and commit to their own significant risk reduction measures.

Recommendation #19: Expand Margins of Safety within High Risk Pesticide Use Patterns to Acceptable Levels over a Two-year Cycle

To achieve its goal of advancing safe, effective, and affordable pest control systems, DPR must regain a greater degree of control over how it directs its efforts. In order to do so, it will have to revisit several policies and procedures, including some that will require legislation to alter, with a special focus on how to deal with the mountain of data and large number of label amendments coming in the wake of EPA's reregistration process.

We recommend that DPR's Environmental Monitoring/Pest Management Branch (EM/PM) be given responsibility for organizing and bringing to closure a DPR-wide effort to identify an initial target list of high risk use patterns. This list will reflect the intensity of pest pressure on a given crop or location, the range of choices farmers and pest control specialists have, the annual volume of pesticides applied, and the percent of volume accounted for by high risk pesticide products (especially the percent used through methods of application known or suspected to lead to excessive human exposure or damaging environmental loadings). In compiling the list, a DPR-wide team should include colleagues from the Medical Toxicology, Worker Health and Safety, and Enforcement Branches. Office of Environmental Health Hazard Assessment (OEHHA) specialists should also be active partners in this process.

Once a preliminary list of high risk use patterns is available, DPR should seek comments and guidance from experts in the state on an annual basis, with the goal of establishing at the beginning of each year a list of about 12 high priority use patterns. The DPR-wide team should include among the criteria it uses in establishing and updating a priority list of high risk pesticide products --

* Documented instances of pesticide poisonings or measured levels in the environment above safe levels

- New information about potential risks from adverse effects reports or from other data flowing into DPR

- EPA's schedule for completion of Reregistration Eligibility Documents or special reviews

- Major pesticides used within high risk use patterns

Just as in the case of high risk use patterns, *we recommend* that DPR try to restore within 24 months adequate margins of safety for all high risk pesticide products used within high risk use patterns. A 24-month cycle would allow about one year for data collection and review and a second year to craft risk mitigation measures and put them in place.

Recommendation #20: Develop Better Ways to Reduce Risk Incrementally

Long before regulators know everything they want to know about a pesticide product's risk profile, they generally know more than enough to want to act to reduce risks associated with its use. This is especially true when regulators expect to be challenged administratively and/or in court by hostile registrants and growers.

But, in reality, often years pass before regulators can put together strong enough risk assessments to withstand concerted criticism and contrary evidence from registrants. For this reason, *we recommend* that DPR and EPA -- individually *and* jointly -- devise new administrative mechanisms to provisionally reduce risks on an incremental basis. These mechanisms will need to be designed to minimize differences in timing and content between EPA and DPR actions, since the number of affected labels is sure to increase sharply throughout the rest of the 199Os, until the reregistration process reaches closure.

Current law and policy suggest a possible course of action. Conditional registrations are granted now to allow a new active ingredient, or major new uses of old chemicals, to move onto the market in the absence of complete information. This makes sense when it allows a safer pesticide onto the market earlier than otherwise would be the case. A similar mechanism is needed in the case of needing to reduce risks incrementally *before* the data needed to fully and accurately quantify risks

and craft final risk mitigation measures have been generated. In implementing such mechanisms and exercising such authority, *we recommend* that DPR and EPA --

- Act sooner to require adoption of low-cost and proven risk mitigation measures, even when DPR suspects additional steps will probably be necessary later
- Require field monitoring data to be generated in the next production season to more precisely gauge the actual impact of risk mitigation on exposure levels
- Relax risk mitigation measures when field data demonstrate that margins of safety have in fact been increased beyond the target level

Incremental approaches to risk mitigation have the potential to lower the cost of novel strategies to reduce risks in a given season. They also may encourage registrants, applicators, and growers to become more innovative and entrepreneurial in devising pest management systems and pesticide use patterns which are both safer and more effective than existing practices. Unfortunately, given present policies and procedures governing the label amendment process, both regulators and registrants may resist incremental risk reduction -- despite its intuitive appeal -- because of cost concerns.

BETTER DEPLOYMENT OF RISK ASSESSMENT RESOURCES

Despite the heavy workload DPR scientists have had to manage since the mid-1980s, the program maintains a steady flow of actions and completes in-depth risk assessments on some potentially high risk pesticides each year. Still, DPR needs to be more aggressive and efficient in screening data quickly for signs of trouble and then focusing its scientific resources on those pesticides for which there are significant new concerns about risk.

Successful ways to screen available data on chemicals quickly and to make preliminary judgements regarding cancer potency have recently been pioneered by other California agencies playing a role in the implementation of Proposition 65 (see Appendix 5 for more discussion). Similar but less structured screening methods are now being used by various DPR and OEHHA committees.

DPR's Adverse Effects Advisory Panel (AEAP) sets priorities for pesticide risk assessment conducted under the mandates of SB 950. The Panel places each active ingredient in one of three categories for risk assessment: high, moderate, or low. This judgement is based on the adverse effects noted in the studies, levels at which they occur, what is known about the quantity of use of the pesticide in California and likely levels of exposure, and the results of risk assessments done by others on the same or a similar chemical.

An October 18, 1991 memo to the Pesticide Registration and Evaluation Committee from DPR's Medical Toxicology Branch lists 46 pesticide active ingredients in the high priority category, 37 in the medium, and 39 in the low priority category. Since 1987, DPR has completed risk assessments on 29 pesticide active ingredients, or just under six per year on average. But, of these 29, 18 involved only one or a limited set of use patterns.

With current resource levels, DPR's Medical Toxicology Branch projects the ability to complete comprehensive risk assessments on 10-20 new or old active ingredients each year. In California in recent years, 3-5 new active ingredients have been registered annually. Accordingly, under existing policies and with stable resources, DPR will be fortunate to complete risk assessments on about 10 old active ingredients per year. On this basis, DPR expects it will take a decade or more before risk assessments will be complete just on the high priority active ingredients from the first 200 pesticides included in the SB 950 data call-in process.

Another Mountain of Work from the East As EPA moves along with the reregistration process, DPR will face -- annually -- hundreds of proposed label amendments for products containing the dozen or more major active ingredients for which EPA completes Reregistration Eligibility Documents (REDs). Under current policies, most of these label amendments will require review also by DPR. The supporting data for any given active ingredient will encompass a hundred or more studies, so DPR's future decisions regarding the nature and scope of review it will conduct on reregistration data sets are significant. If the Legislature were to *mandate* such reviews, the resource implications would be dramatic.

While California-only data requirements will pull thousands of studies into DPR in the next decade, the truly sobering volume of data is being generated in response to EPA's reregistration process. Under current policies, DPR will be requesting and reviewing all the studies submitted to EPA *plus* California-only studies, when required, as revised product labels are submitted for DPR's approval.

EPA statistics lend perspective on the volume of data DPR can anticipate. As of January 1992, EPA had received 13,000 studies in support of List A and B chemicals including, by discipline:

- 4,600 toxicology
- 3,800 residue chemistry
- 2,500 environmental fate
- 2,500 ecological fate

While impressive, these numbers are dwarfed by the number of additional studies already underway that will be submitted to EPA over the next five or so years. For just the 175 active ingredients on EPA's reregistration List A, Table IV. 1 presents summary data as of February 21, 1992 on the number and percent of guideline studies that are required and currently satisfied. Clearly, EPA and DPR have seen only the tip of the iceberg.

Table IV.l: Studies Needed on List A Chemicals to Satisfy Basic EPA Testing Guidelines: By Major Area (February 21, 1992)

	Total Required	Number Satisfied	Percent Satisfied	Number Not Satisfied	Percent Not Satisfied
Guideline Area					
Core toxicology	541	127	24%	409	76%
Non-core toxicology	955	243	25%	671	70%
Re-entry and farmworker exposure	140	5	4%	121	86%
Environmental fate	1,634	126	8%	1,376	84%
Ecological effects	1,245	221	18%	969	78%
Residue chemistry	3,371	121	4%	3,191	95%
Product chemistry	2,116	476	22%	1,624	77%
TOTAL (all areas)	10,178	1,325	13%	8,529	84%

SOURCE: Registration Status Report -- List. Data as of February 21, 1992, provided by Special Review and Reregistration Division, OPP/EPA.

As of February 1992, EPA had received a total of 11,072 studies on list A chemicals. Of these, just over half had not been reviewed. Of the 5,705 studies that had been reviewed, 2,540 were found not to have fully satisfied the data requirements -- representing a rejection rate of 44.5 percent. Of these rejected studies, some are now (or will be considered) supplementary studies,

thereby lessening the scope of additional data registrants will have to submit to satisfy the requirements. Nevertheless, for up to four in 10 studies EPA already has reviewed, the agency will be receiving additional data to review at some point in the future. On the positive side, EPA has complete core toxicology data packages, which have been reviewed, on 40 List A active ingredients.

The mountain of new data in the mid-1990s probably will be followed by another by the end of the decade. EPA is moving closer to promulgating new toxicological testing requirements for neurotoxicity, immunological effects, and acute toxicity. Also, new reproductive and developmental studies will no doubt be called for as public concern is focused on potential risks of pesticides in the diets of infants and children, the topic of a long-awaited National Academy of Sciences report due out in early 1993.

Recommendation #21: Focus Data Requests Strategically on High Priority Concerns

As DPR's most pressing problem shifts from not enough to too much data, the Department will need to develop the capacity to prioritize the universe of pesticides for which new data requirements apply. Whether toxicology, environmental fate, wildlife, or exposure data, when DPR is mandated or chooses to request that registrants develop and submit more data, *we recommend* that DPR do so surgically as opposed to comprehensively.

Targeting requests for new data makes sense for several practical reasons. The more data DPR has to review, the longer it will take to get the job done; and the more likely that worrisome questions about studies will not be fully explored. Registrants also tend to become combative when they feel regulators are imposing unwarranted data requests upon them. These outcomes slow down the pace of identifying the need for and nature of risk mitigation practices. Also, DPR efforts to recognize excessive risks will be more successful if the scientific resources of DPR *and* registrants are targeted to *augment* -- not just duplicate -- EPA's typically more comprehensive data call-in and scientific review processes.

Recommendation #22: Develop Methods to Screen New Data Packages for Surprises and Target Scientific Review Resources

With 30,000 or more new studies likely to arrive in the decade ahead, and many more risk assessments needed than it can hope to complete, DPR must develop the capacity to target its scientific review and exposure monitoring resources. Toward this end, *we recommend* that DPR --

* Continue targeting resources to studies reported by registrants as showing a heretofore unknown adverse effect

- Develop preliminary rankings of all chemicals on the basis of:
  -- Human toxicity

-- Exposure pathways

-- Extent of use in California

-- Environmental risks

-- Vulnerable subpopulations such as infants, pregnant women, and the elderly

Implementation of Proposition 65 required California state agencies to develop and apply expedited methods to assess a chemical's oncogenic potential. We *recommend* that Cal-EPA and DPR extend this capability to a broader range of health effects and use it to conduct quick, preliminary screens of pesticide toxicity as new data generated in response to SB 950 flow into DPR. ***We further*** *recommend* that a joint DPR-OEHHA committee be given the task *and resources* to --

- Compile a matrix of currently available DPR and/or EPA acceptable daily intakes (ADIs), reference dose (RfD), or potency factors by active ingredient for major end-points of concern, along with identification of the specific toxicology study used in setting the ADI, RfD, or potency factor

- Seek EPA review and input on this matrix -- or joint development of it -- to assure that it reflects EPA's current understanding of pesticide toxicity

- Develop mechanisms to complete within a month, on average -- as a goal -- a preliminary screen of new toxicological data that are sufficient to determine whether major changes may be warranted in EPA's existing ADIs, RfD, or potency factors used by DPR in determining margins of safety

- Develop, test, and refine new screening and preliminary risk assessments techniques to apply to new types of data and endpoints

Last, *we recommend* that DPR couple new screening mechanisms with revised internal policies governing the order and depth of reviews. Some studies should be routed directly into full review and possibly risk assessment; others should pass through the system without further attention, with DPR relying principally on EPA's evaluation of the data and assessment of risks. To make this a practical option, EPA will need to provide **DPR** scientists easy access to EPA scientific review and risk assessment documents. In making decisions about which studies to review in depth, DPR should take into account the quantity of product used in California, records of illnesses and exposure levels, and other information relevant to risk scenarios and factors which are possibly unique in California.

Recommendation #23: Clarify and Expand Adverse Effects Reporting Requirements to Cover All Potential Exposure Pathways and Risk Concerns

Like EPA, DPR has in place an adverse effects reporting requirement which directs registrants to flag and quickly submit any studies or other information demonstrating adverse effects at lower levels than in previously submitted studies. *We recommend* that DPR reviewers continue to focus immediately on these studies.

The problem with this policy at the state and federal level is the degree of ambiguity that remains regarding which studies and sources of information need to be reported under it by registrants (or "flagged," to use EPA's terminology). Based on a review of recent DPR actions and interviews with scientists both in DPR and EPA, it appears that --

- Some registrants are reporting/flagging many more studies than necessary, either out of misunderstanding or a desire to assure quicker reviews
- Certain studies showing adverse effects are not being properly reported/flagged
- Some flagged studies submitted to EPA are not being reported when submitted to DPR, and vice versa

As the forthcoming mountain of data overloads EPA and DPR reviewers, the importance of a clear and vigorously enforced adverse effects policy will intensify. Both DPR and EPA know there are still problems with the current policy and that other problems will arise as the policy is extended to other exposure pathways (such as groundwater or air) and other endpoints (such as fish-kills or the fate of microbial pesticides in the soil).

EPA has recently reviewed and proposed revisions in its adverse health effects reporting requirement. Before the changes are finalized, EPA should work with DPR to eliminate ambiguities regarding which studies need to be flagged when submitted to EPA and reported when submitted to DPR. *We recommend* that DPR --

- Review EPA's changes and adopt those that will clarify DPR's policy
- Offer recommendations to EPA regarding criteria and standards that will address problems DPR feels may persist even with EPA's proposed policy revisions

The most complex issue in refining EPA/DPR's adverse effects policies is specifying the criteria which registrants are to apply in determining whether a given study or incident in the field demonstrates an adverse effect that is different enough to warrant flagging or reporting. This is tricky because nearly all toxicology studies, by design, will demonstrate some adverse impact, and

it will often be unclear -- and impossible to sort out after the fact -- what happened in certain field situations.

To the extent possible, *we recommend* that DPR and EPA adopt clear, quantitative criteria that refer to a study's impact on an active ingredient's current acceptable daily intake, reference dose, or margins of safety. Registrants could be required to flag/report any study that would lower such levels by more than one-half, based on standard EPA risk assessment methods. Any study demonstrating a significant new human health or environmental risk should also be flagged/reported.

Moreover, in light of DPR's basic mission -- assuring safe, affordable, and effective pest control systems -- ***we further*** *recommend* that DPR clarify or extend its current adverse effects reporting requirement to include other types of information indicating that a pesticide product has caused unexpected problems. Such problems may involve impacts on nontarget species (fish, wildlife), secondary pest problems, or lost efficacy due to resistance.

Last, we *recommend* that DPR and EPA adopt a reciprocal requirement that will resolve any ambiguity regarding whether a given study needs to be submitted to EPA, DPR, or both.

SHARING THE RISK ASSESSMENT BURDEN WITH EPA

DPR and EPA use scientific information from a variety of sources to support risk assessment and guide risk mitigation. (EPA uses the term "risk management" instead of "risk mitigation," the term most frequently used by DPR.) Risk assessment relies heavily on information supplied by pesticide registrants. In reviewing submitted data, DPR and EPA scientists look for evidence of adverse effects on the test organism, focusing in on the effect that occurs at the lowest dose level. The lowest dose where an adverse effect is observed is then used in estimating a *reference dose* in humans, unless there is either a pharmacokinetic or physiological reason not to (pharmacokinetic refers to the way a test species absorbs, distributes, metabolizes, and excretes the chemical, in contrast to humans).

A standard safety factor -- usually "times 100" -- is then applied to extrapolate from animal experimental data a safe level for human exposure. Such estimates are referred to alternatively as acceptable daily intakes, reference doses, or safe levels. The meaning in all cases is the same: a level of exposure below which regulators do not expect to see similar symptoms in humans. This methodology for setting safe levels is generally not applied for chemicals that are genotoxic (cause damage to DNA) or for which there is no known threshold of exposure below which an effect is not expected or observed.

Quantifying Risk in California When carrying out a dietary risk assessment, EPA includes California within the analysis. It does this by using national food consumption surveys and average residue levels expected following treatment of crops with pesticides -- including crops grown and

consumed in California, as well as those shipped into the state. In general, EPA's dietary risk assessments are as complete and sophisticated as possible in evaluating chronic hazards, given available data. There is greater uncertainty regarding how EPA is currently carrying out dietary risk assessments for certain acute effects. The agency's policies and scientific procedures in this area are, according to an agency scientist, "in a state of flux."

EPA risk assessments are less complete and accurate in addressing other sorts of risks, especially occupational and environmental risks that vary tremendously across the nation. These non-dietary sources of risk vary so much because of diversity in the physical, climatic, and technological landscape of American agriculture.

To its credit, DPR has invested its risk assessment resources strategically, focusing most of its efforts on the vast range of occupational risks arising from California's high value, diverse agricultural sector. The majority of these risk scenarios -- hand weeders in an onion field treated earlier with an insecticide, irrigation ditch workers using a shovel all day around a field treated with a soil fumigant -- receive scant attention by EPA.

With the volume of SB 950 and FIFRA reregistration data beginning to flow into DPR and EPA, respectively, an even more systematic approach will be needed to avoid severe data overload, and chronic delays in completing actions -- including actions needed to get safer pesticides onto the market quicker and risky ones off faster. Moreover, state and federal taxpayers would be well served if EPA and DPR (as well as regulatory agencies in other states) could work out ways to share at least some parts of the workload.

Right now, EPA strives to assess and manage all risks comprehensively, with the exception of groundwater and endangered species risks which, because of their state-specific nature, EPA has proposed delegating to the states to manage through EPA-approved state plans. In California, now that DPR is implementing its new statutory mandate to conduct dietary risk assessments and mitigate excessive risks, DPR's portfolio is essentially as broad as EPA's, except for EPA's international programs and policies.

Recommendation #24: Recognize and Pursue Areas of Specialized Expertise and Responsibility

> *"It would be particularly helpful if DPR developed specialized expertise in the area of inert ingredients. In terms of assessing the safety of end-use pesticide product formulations, this expertise is critical."*
>
> -- Environmental Activist

The expanding purview of DPR risk assessment activities has been in response to a series of new laws passed in California largely because of impatience with the pace and quality of EPA's decision making. Notwithstanding past shortcomings and existing laws, the California Legislature and the U.S. Congress should look ahead in an effort to identify the basic and essential elements of a workable federal-state partnership in regulating pesticides. There is plenty of work to go around even if all of it is optimally shared. EPA should continue to focus its scientific resources on clearly national issues and concerns. To support state program efforts, *we suggest* that EPA assume principal responsibility for dietary exposure and risk assessments and hence --

- Develop national dietary consumption estimates for all foods and mixtures, including food consumption estimates for different population subgroups and at varying levels of confidence (that is, estimates of average, mean, 70/90/95 percentiles of consumption among eaters of a particular food only, as well as all consumers)

- Maintain an up-to-date data base of published tolerances and measured residue levels found in food, along with the agency's most recent estimates of anticipated residues for all pesticide-crop-food combinations

- Calculate dietary exposure estimates for all pesticide-crop-food combinations, using the data and methodology described above

- Explain how to estimate exposure and risk from residues found in water

Drawing on the Dietary Risk Estimation System (DRES), EPA should offer the states their choice of a computer file that contains the above information, the raw data files and basic programs needed to calculate estimates of exposure, or pesticide- or crop-specific data. State regulatory agencies, including DPR, should use EPA's data and system as a point of departure in any dietary risk assessment they do and seek EPA's guidance in adding new data or modifications to the system.

We also suggest that EPA take the lead in the next phase of dietary risk assessment -- calculating for each pesticide the potency factor, or other estimate of toxicity, that will be multiplied by exposure to yield an estimate of risk. While the endpoint of the dietary risk characterization process is a single number, the process needed to derive this number is a long and complicated one.

Moreover, EPA needs to develop its capacity to more comprehensively assess active ingredients, major metabolites, and inert ingredients in carrying out dietary risk assessments.

No state regulatory agency, including DPR, has the breadth of scientific staff resources to match the job across all pesticides and inerts that EPA does in evaluating core toxicological data sets for the purpose of dietary risk assessment. Therefore, we suggest that EPA --

* Compile and make available to states a listing of all food use active ingredients which has three information items:
  -- Potency factor/reference dose or other measures of toxicity EPA has available to use in risk quantification

  -- Study and toxicological effect of concern that is the basis of the potency factor

  -- Method or model EPA used to translate an observed effect in an animal study to a potency factor for use in estimating human risk

  -- Inert ingredients of potential concern, and their toxicological properties

Recommendation #25: Support DPR's Efforts to Develop Specialized Expertise Applicable to National Problems

> *"We have had very few problems with the studies generated to meet California data requirements. In fact, they have often provoked us to deal with high risk use patterns much sooner than we had anticipated, given our reregistration schedule."*
>
> -- EPA Data Review Manager

By law, DPR has to concern itself with all risks associated with pesticide use in California. Common sense and the volume of work involved dictate that DPR focus on risks likely to be serious and unique to the state. Even when so focused, however, DPR's purview is very broad. It encompasses risks facing all living organisms, surface water and groundwater quality, and atmospheric exposure and deposition, including drift onto adjoining fields. In addition, DPR must focus a significant portion of its resources on risks associated with nonagricultural use patterns, including many which bring pesticides and people into contact in the home, at work, and while enjoying the outdoors. Both nationally and internationally, DPR has been in the forefront of efforts to develop more accurate and realistic exposure assessment methods, particularly in the case of farmworker and applicator exposure. Its work has led to several widely accepted improvements in field study design and dosimetry (monitoring method to determine levels of dermal exposure), improvements now used routinely by EPA.

We suggest that EPA more systematically rely on DPR, and other state regulatory agencies as appropriate, to advance the accuracy of exposure and risk assessments involving farmworkers and

applicators, water-based hazards, and ecological impacts. While DPR has data and opportunities to study occupational exposure only in California, it has advanced the state-of-the-art accessible to EPA and other states. Accordingly, if EPA were willing to provide additional resources to DPR to assure that the Worker Health and Safety Branch does not slip behind in its primary mission, DPR could develop and make available to EPA -- and EPA to other states:

- Practical suggestions on how to design and carry out farmworker exposure assessments, fully referenced to and reflecting EPA guidelines

- For pesticide-crop combinations known to result in significant applicator or farm-worker exposure:
  -- A summary and review of field re-entry intervals, foliar residues levels, and/or maximum safe levels of exposure over a particular time as recommended or required by DPR, EPA, or other regulatory bodies

  -- An explanation of factors to watch out for in assuring a given interval or level will provide adequate protection under specific climatic, soil, and agronomic practices

  -- The route of exposure and health effect of greatest concern, as well as the toxicological potency factor to use in translating estimates of exposure to margins of safety for both active ingredients and inerts of concern (these factors should be derived collaboratively by DPR and EPA)

- Methods to estimate the impact on applicator exposure of various changes in pesticide mixing, loading, and application methods, machines and technologies, including the percent of exposure reduction in various circumstances expected from protective clothing, gloves, various types of respirators, and other common safety precautions

Recommendation #26: Share the Risk Assessment Load to Speed Progress and Tailor Risk Mitigation Measures to Unique State-specific Needs

Identifying and reducing pesticide risks could be done better and faster if the workload were shared systematically rather than replicated routinely, as is now the case. Recent discussions between EPA and DPR to identify candidate tasks for joint reviews, or the sharing of certain aspects of risk assessment, should be brought to closure so that pilot efforts can move forward.

Over time and with experience, DPR and EPA should work toward reciprocal agreements whereby one agency takes on a task and the other accepts the outcome with limited additional

review. The division of risk characterization and quantification responsibility could be done on the basis of a set of principles to --

- Identify those aspects of the risk assessment process that can be carried out by one agency on behalf of both

- Decide which review tasks should generally be EPA's responsibility and those which DPR should routinely accomplish

REDIRECTING RESOURCES TO HIGH RETURN ACTIVITIES

Some DPR activities are more important than others in generating new insights into patterns of risk unique to California, in expanding pest management alternatives, or in refining the reliability of various risk mitigation measures. Developing the capacity to direct more resources to high return activities is a compelling reason to develop new priority-setting mechanisms. It is also a good reason for DPR and EPA to more effectively coordinate and share the workload.

Expanding Field Level Expertise The level of existing DPR resources available to design and carry out field-level monitoring and investigative studies is dwarfed by the number of pesticide use patterns which are in need of more careful study. Because DPR and registrants place great faith in the effectiveness of risk mitigation practices, both DPR and registrants bear an obligation to potentially exposed populations to be sure risk mitigation practices are in fact adhered to and work as well as hoped. Meeting that obligation requires that DPR focus additional registrant resources on the exposure-related consequences of how pesticides are being handled and applied. Similarly, better real-time information needs to be obtained on residue levels remaining on crops in the field or on harvested commodities with which workers on the farm or in packing and processing plants come into contact.

Specialized Expertise DPR deserves praise and national recognition for its contributions to development of methods to characterize and quantify pesticide risks faced by applicators and farmworkers. Progress has been made through frequent contact with public health experts in the field, steady investments in pesticide illness surveillance and reporting, and field-level research activities -- generally with growers and sometimes supported by academic cooperators. At present, most applicator and field-worker exposure estimates are carried out by the Worker Health and Safety Branch, with input from the Enforcement Branch. DPR's emphasis is on assuring that actual field level practices -- the way people carry out tasks while handling pesticides or when in recently treated fields -- are taken into account in estimating exposure.

It is particularly important for DPR to continuously assess the likelihood that sophisticated pesticide mixing, loading, and application equipment is used properly. In addition, the Enforcement Branch needs to refine the methods it uses to assure that timing-based risk mitigation practices --

especially field re-entry intervals -- are routinely adhered to in practice. DPR should use this same basic approach in developing special expertise in other key areas where better, more timely information will produce better decisions. For example, in collaboration with CDFA and other appropriate state and federal agencies, DPR should investigate --

* The extent and rate of change in pest population resistance to pesticides

- Circumstances and practices causing secondary pest outbreaks or otherwise setting back efforts to successfully adopt IPM systems and biological control methods

- Locations around the state where aquifers are vulnerable to contamination (an investigation of this type is currently underway)

- Strategies to time and carry out pesticide applications to protect wildlife and other nontarget organisms

- Drift, dormant sprays, and toxic fog -- particularly in densely populated coastal areas, where high-value fruit and vegetable crops thrive

Financing New Initiatives Particularly over the next decade, as DPR and EPA work through the resource-intensive phase of reregistration, more staff resources will be needed to keep the process from grinding to an exceedingly slow pace. Without new resources and streamlined procedures, the volume of data on the way and the thousands of related decisions will strain DPR's capacity for field-based research activities -- one of the highest return activities DPR carries out.

DPR should seek from the Governor and Legislature and the registrant community sufficient resources to keep up with its workload, allowing no further slippage in average response times. Speedier action is needed both to calm public fears and to capitalize on the enormous investment that is being made in new data.

Recommendation #27: Refine Exposure Assessments through Field Monitoring and Enforcement Activities

DPR's capability to identify pesticide use patterns that are riskier than previously thought is heavily dependent on accurate information regarding what is actually going on in the field. Both grower groups and registrants, as well as farmers, applicators, and field-workers, will benefit from greater understanding of pesticide exposure patterns.

The science needed to develop this understanding can be complex but is not as costly or time-consuming as other core toxicology studies. More accurate exposure studies will lead directly to more definitive risk assessments, which DPR can then rely upon to calibrate risk mitigation efforts

and assure their effectiveness in practice. Everybody gains from such progress. Toward this end, *we recommend* that DPR --

* Require registrants to invest more resources in real-time, field-level investigations to develop exposure profiles under common, current practices, as well as following adoption of proven, accessible risk mitigation practices

- Train and encourage pesticide enforcement and investigative staff, including individuals working for county agricultural commissioners, to monitor those field practices which are expected to affect actual exposure levels

PROGRAM ACCOUNTABILITY AND COMMUNICATION CHALLENGES

As it is for EPA, accountability to the public is an essential obligation DPR must sustain in order to keep public reaction to its major decisions within reasonable bounds. Disclosing the technical product-oriented and scientific data on which decisions are made is one positive step regulators can and should continue taking. A complicating factor in meeting the obligation of accountability is the legitimate right of registrants to keep certain pieces of information confidential and proprietary -- for example, the statement of formula for a pesticide and its manufacturing process. When only a few companies sell a given product, sales and production data are also treated as confidential.

For the vast majority of Freedom of Information Act requests at the federal level, as well as for requests in California under its public disclosure act, there is no need for or interest in obtaining confidential business information (CBI). Still, both EPA and DPR have to proceed carefully to assure that CBI is not inadvertently disclosed.

DPR needs to minimize the odds of inappropriate disclosure by requiring registrants to isolate, package together, and highlight all CBI sent in with a submission. This file would then not normally be subject to disclosure. At the same time, the Director should retain and not hesitate to use existing authority that allows release of a pesticide product's confidential statement of formula to any physician or public health organization that needs access to it for medical reasons

Data Compensation In managing the volume of data DPR can expect in the next decade, DPR should seek to lighten its administrative burden to the extent possible by minimizing problems with data compensation and the disclosure of confidential business information. Both these prospective problems arise from federal requirements imposed on state cooperating agencies as well as state law.

Data compensation involves a statutory scheme whereby companies who wish to rely on another manufacturer's safety and health data to satisfy registration data requirements may do so --

after a period of exclusive use expires -- by offering to compensate the data developer. Regulators should avoid being drawn into the role of keeping track of such private sector agreements and dealing with instances in which disputes arise about who owns which data and who is obligated to pay specified amounts to whom. If the California Legislature believes registrants should receive compensation or special protections for data submitted to DPR, as it has called for in some circumstances, the Legislature should consider authorizing establishment of a joint powers authority, or other private sector mechanism, to sort out these concerns outside of DPR.

At the federal level, experience with data compensation has been negative. EPA has found the policy to be an administrative headache; registrants criticize it as an ineffectual mechanism subject to very high legal and transactions costs; and few people think it helps achieve its basic goal of encouraging innovation and competition in the pesticide industry by facilitating market entry by establishing a compensable right in safety and health data.

Inconsistencies Since hundreds of people are involved in carrying out pesticide regulatory functions, some degree of inconsistency is unavoidable. For example, DPR has developed precise and detailed instructions regarding how submissions are to be presented. These instructions make it possible for DPR's registration specialists to route the packages through internal review stations efficiently. Some registration specialists, however, reject packages for minor deviations from the required format, triggering a letter to registrants that outlines the deficiencies and options for overcoming them. Finding similar deficiencies, other specialists just pick up the phone and explain the problem, hoping registrants will respond positively by providing whatever is needed to bring the package into compliance with DPR's requirements.

> *"Uneven, and too often poor enforcement in some counties is a major problem for us in buying into complex DPR risk reduction measures. Also, people will be people, and some just think they know better or are invincible. The real pros out there are pretty careful and do a good job, but there's too many cowboys that just don't care."*
>
> -- Scientist working on farmworker protection

Inconsistencies also arise in county-level enforcement efforts. Differences reflect the vigor, community support, and resources available in each office of the county agricultural commissioner, as well as how pesticide enforcement fits into each office's overall priorities. Just as differences between the state and federal governments sometimes become an issue, so too can differences in the way two adjoining counties enforce state regulations. Many California farmers and agribusinesses produce crops in more than one county and are perplexed when they are allowed to carry out a practice in one county but not the other. For crop consultants, commercial applicators, and pesticide dealers who also generally work in more than one county, differences in the way counties interpret and enforce DPR's rules can fuel ridicule and create real problems in record keeping and compliance.

CHAPTER V: SAFER PEST CONTROL SYSTEMS

DPR's scientific efforts and regulatory tools are designed to validate the presumption that a pesticide will be safe if used in accordance with its label directions. The challenge of the 1990s is to design pesticide regulation that can lead to safer pest control in agriculture. Because DPR's focus is on individual products, it has been able only indirectly to advance the development and adoption of safer pest control systems.

> A ***safer pest control system*** is a relative term that encompasses most integrated pest management and biocontrol systems. It refers to a system of pest management that, relative to other more pesticide-intensive control systems, successfully incorporates use of plant genetic, cultural, and biological control methods as a first line of defense.

Under current law, DPR's regulatory mission and tools are intended to assure first that, when a pesticide is used, it will not harm people or the environment and, secondly, that it will kill or otherwise control the target pest. To achieve the broader goal of encouraging adoption of safer pest control systems, DPR must evaluate a pesticide's proposed use pattern and impacts within the biological system in which it has been approved as a tool for crop protection. This approach is in keeping with the following goals laid out for Cal-EPA in Governor's Reorganization Plan #1:

- "Target the greatest risks" -- DPR should focus its scientific resources and regulatory interventions on high risk conventional pesticides and use patterns
- "Stimulate the private sector to advance safer technologies" -- DPR should streamline reviews of biorational control products and relax regulatory requirements for inherently safer products
- "Prevent pollution" -- DPR can encourage, and in special cases require, that pesticides be used within integrated, biologically-based systems

> A ***safer pesticide product*** is a relative term, used to denote a pesticide product with one or more desirable physical, chemical, toxicological, biological, or ecological properties relative to other registered pesticide products or non-chemical control alternatives.

Regulation can become part of the solution to California's long run pest control problems by making the regulatory climate progressively more comfortable for pesticides with desirable chemical and biological properties and less forgiving for conventional, broad spectrum pesticides that are more difficult to use safely.

Timing is critical: safer alternatives should be proven and available before the use of existing, higher risk alternatives is restricted.

IDENTIFYING SAFER SYSTEMS OF CROP PROTECTION

The effectiveness and affordability of biologically-based crop protection systems depend on growers' having access to a diverse array of specialized pest control tools: chemical, genetic (pest resistant plant varieties), and biological. These tools must be incorporated skillfully on a site-specific basis, with the benefit of real-time information on pest-crop interactions in a given field if pest populations are to be maintained below economic thresholds.

The same concepts and approach offer promise in managing environmental risks, such as surface water or groundwater contamination. Indeed, DPR's Environmental Monitoring and Pest Management Branch (EM/PM) has carried out several successful projects which resulted in the design and refinement of integrated farming, water management, and pest control systems. These projects have helped growers and pest management experts expand their options, and they have enhanced DPR's capacity to use regulation to promote safe, effective, and affordable pest control systems.

DPR already has taken tentative steps toward regulating the components of pest management systems. An illustrative example follows -- the management of rice pesticide levels in the Sacramento River system.

A SYSTEMS-BASED SUCCESS STORY: THE RICE HERBICIDE PROGRAM

Some of the most complex and immediate pesticide water quality problems in California arise in connection with intensive rice production in the Sacramento Valley. In 1982, in the Sacramento River drainage system below the rice fields, an estimated 28,000 fish were killed by concentrations of the rice herbicide, molinate (trade name: Ordram). The peak level of molinate found in drainage water in 1982 was 697 parts per billion (ppb) -- well above the level thought at the time to be protective of fish species (90 ppb).

Efforts to correct water quality problems resulting from rice pest control were set in motion by the state Department of Fish and Game and the City of Sacramento, which presented evidence of surface water contamination to DPR's Pesticide Registration and Evaluation Committee. The State Water Resources Control Board (State Water Board) and the Regional Water Quality Control Board (RWQCB) played roles in overseeing the program.

DPR's activities were part of a broad interagency state and local program to reduce the presence and significance of rice herbicides in the Sacramento River drainage system. A first step, led by DPR's EM/PM Branch, was to study, understand the sources of, and figure ways to reduce

the levels of pesticides entering the surface water system from rice fields. Initial efforts evolved into DPR's Rice Herbicide Program, which began in 1984. The program's objectives were to --

- Establish science-based risk reduction goals tied to maximum allowable contaminant levels in water
- Design an integrated crop-water-pest management program to reduce pesticide levels consistent with water quality goals
- Agree on how and where to measure and monitor progress in meeting the goals
- Conduct cooperative research and monitoring efforts to determine where and how additional reductions could be brought about
- Achieve a high level of grower compliance with required risk reduction measures

The program also included annual reevaluation of the water quality goals themselves in light of observed adverse impacts, if any, from the levels measurably achieved in the previous year. In 1992, for example, the water quality goal for molinate has been lowered to 10 ppb in order to protect more sensitive aquatic species in the Sacramento River system.

Program Accomplishments The total mass transport of molinate -- that is, the weight of pesticide flowing off rice fields and down the Sacramento River -- was estimated to be 40,667 pounds in 1982. In 1991, new management practices had lowered mass transport to just under 220 pounds (a remarkable 99.5 percent reduction from 1982) and without any appreciable impact on the level of weed control achieved. For thiobencarb (trade name: Bolero), similarly dramatic reductions have been attained in average concentration levels and mass transport.

In 1992, the RWQCB staff reported that, of 4,175 inspections of Sacramento Valley rice fields for compliance with water holding requirements, only 28 violations were noted. Through analysis of its enforcement and field research data, DPR discovered that holding pesticide-treated water on the rice fields (or within closed irrigation tail-water systems and ponds) for a minimum of 24 days allowed pesticides to dissipate almost entirely before the tail-water was discharged into channels emptying into the river.

Furthermore, DPR compiled evidence in 199 1 that aerial drift into drainage ditches adjoining fields contributed to the presence of rice pesticides in surface water. Because most rice pesticides are applied by air, drift into adjacent surface water is inherently a potential problem. However, until 1991, pesticide discharges from fields had overwhelmed the Department's ability to detect and measure aerial drift. Following interactions with county agricultural commissioners (CACs), aerial

applicators, and pesticide enforcement staff, DPR designed and incorporated drift control measures into the 1992 rice pesticide program.

THE RICE HERBICIDE PROGRAM
Meeting Water Quality Goals

	1982	1991
Peak level of molinate in drainage water [parts per billion, or ppb]	697	26
Peak level of molinate at drinking water intake [ppb]	16	0.6
Applicable maximum contaminant level, or mcl, for drinking water	20	20
Mass transport of molinate in Sacramento River [in pounds]	40,667	220 (-99.5%)

Steps in the Process. The Rice Herbicide Program achieved dramatic results by following a *set* of procedures which will surely be applicable in the future for regulators who are charged with protecting environmental quality. Specifically, the steps taken by DPR included to:

1. Set *Goals* DPR asked the Department of Health Services (DHS) and the Department of Fish and Game (DFG) to develop guidelines for protection of public health and aquatic organisms. The RWQCB and DPR subsequently adopted these guidance values as appropriate for the protection of beneficial uses of surface water.

2. Measure, Monitor, and Report Results The cooperating agencies designed an annual sampling program to determine whether the goals were being met. Following this plan and in consultation with university experts and the rice industry, DPR assessed the interactions of irrigation management, pest pressure, and pesticide applications. Every year, the Rice Herbicide Program's results and DPR's recommendations for changes in management practices to further reduce contamination levels are reviewed by the RWQCB to assure they comply with the Basin Plan.

3. Incorporate Success into the Enforcement Program Each year, DPR has required CAC offices to incorporate the selected best management practices into the provisions of the permits granted to growers at the beginning of the season. Since all the pesticides of concern are restricted use materials, growers wishing to use them must have permits at the beginning of the year and must agree to abide by all applicable use restrictions, recommended management practices, and use

reporting requirements. Through the permit process, the CAC offices have worked out with individual growers the water and pesticide management plans they will employ during each season, consistent with the requirements which DPR proposed to the water regulatory agencies.

Regulatory Effectiveness in a Systems Approach California's approach to addressing rice herbicide problems was and remains remarkably effective. It demonstrates the value of finding improved ways to manage pesticides *within the farming systems in which they are used.* It confirms that DPR can design and that the county agricultural commissioners can enforce systems-based plans that allow growers to retain access to pesticides while still meeting environmental quality goals. There is every reason to believe that essential elements of this model can be drawn upon successfully in tailoring similar approaches to address many other high risk use patterns and cropping systems in the state.

Such approaches, however, will often impose significant costs and new burdens on field-level staff, researchers, growers, and DPR. Accordingly, the first step should be a realistic appraisal of resource needs. It will be up to affected growers, communities, registrants, commodity organizations, county boards of supervisors, DPR, the California Governor and Legislature, and possibly even federal agencies to decide whether necessary investments are warranted by the benefits gained and, if so, who should make the investment and from which source of funds.

SAFER PEST CONTROL SYSTEMS

The approach to pesticide regulation in California must shift in focus gradually, from one-product-at-a-time decision making to encouraging adoption of safer pest control *systems. Due* consideration will need to be given to the time requirements for new system-based risk assessment methods and risk mitigation strategies to be developed and refined, as well as the time needed for alternative technologies to be developed in the first place and then moved through the regulatory system, ultimately to be successfully adopted by farmers.

Unfortunately, beyond general agreement that shaping safer pest control systems is a desirable goal, no similar consensus has emerged regarding such matters as:

- What constitutes a safer pest control system -- *safer* relative to what? And how safe?
- What does DPR need to take into account and measure in reaching such judgements?
- How should DPR deploy its regulatory tools toward this new goal, and how should it work with other major players that have integral roles to play if meaningful progress is to be achieved -- players such as CDFA, the university system, growers, food processors, registrants, and other agencies at the state and federal levels?

Caveats Grower acceptance of and commitment to biointensive IPM systems, and related safer systems of pest control, are direct functions of their effectiveness -- whether, in other words, growers feel their investment in a crop is secure under such systems. Few commercial growers are willing or can afford to experiment with their crops to advance general knowledge about IPM and nonchemical crop protection methods. Farmers have to be confident the systems will work, because their livelihoods are at stake.

Still, both researchers and regulators can do more to provide growers and crop protection specialists with tools and guidance designed to improve the chances such systems will work. A critical element in building grower confidence is to assure that there are readily accessible ways to deal expeditiously and effectively with unexpected pest problems when safer systems do not work as well as hoped for. Regulators, in particular, need to direct their attention to meeting this need -- the management of uncertainty -- by assuring that materials remain available for such uses, even materials that might *not* be retained for broader uses.

Both DPR and EPA lack statutory mandates and regulatory tools to shift the focus of regulation to the performance of pest control *systems,* as opposed to individual products. Furthermore, in many key crop-pest combinations, there are few proven alternatives available or even well along in the development process. The capacity of regulators to influence on-farm pest control practices -- other than how a particular pesticide is used -- is therefore both statutorily and practically limited. Under these circumstances, exercising such influence would require partnerships between levels and agencies of government and the private sector that would be characterized by an unprecedented and sustained level of trust and cooperation.

Four Components Four components of regulation are needed to accelerate the evolution and profitable use of safer pest control systems: timely registration of safer products; restricted application of ecologically disruptive products; increased use of genetic, cultural, and biological alternatives to conventional pesticides; and experimental efforts to design and license pest control systems.

Recommendation #28: Assure Timely Registration of Safer Products

DPR's influence over private sector research and investment priorities is limited. But what DPR *and* EPA can do, working *together*, is to accelerate progress along the regulatory path for safer biologically-based products. For example, DPR could rely more heavily on EPA's completed reviews in carrying out its own assessment of new biochemical active ingredients. EPA should strive to complete action on all prospectively safer products within one year. DPR should approve first-time registration applications of safer products within 120 days and then waive (or initiate one month early) the 30-day posting requirement (unless there is reason for concern about potential risks unique to California). In short, because the potential benefits to the public from bringing biorational pesticides to market are great, we *recommend* that DPR and EPA -- both individually and collectively --

Biorational pesticides are typically naturally occurring microorganisms or biochemicals that may be extracted or synthetically produced. Biorationals may also be products of genetic engineering. They are usually more "environmentally friendly" than conventional pesticides and are typically target pest-specific rather than broadly toxic.

- Support widespread experimentation with new pesticides and biorational control technologies, through new Experimental Use Permit policies that accommodate the needs to test biocontrol agents over large acreages to determine factors influencing the level of control achieved and to generate information that will help regulators apply the definition of safer pesticide product

- Reassess insect growth regulators (IGRs) as a group, to identify ways to lessen aquatic risks associated with their use, as well as whether and to what extent incorporating IGRs into safer systems of pest control could reduce the number and rates of applications of insecticides known to pose farmworker, applicator, and avian risks

- Especially for safer pesticide products, facilitate rapid approval and commercial adoption by --
  - Modifying risk-related data requirements in light of a pesticide's prospective toxicity, environmental fate, and the exposure profile expected (given the method of application)

  - Modifying efficacy-related data requirements in response to the properties and proposed use patterns of a chemical

  - Seeking and entertaining suggestions from registrants regarding how efficacy field trials should be designed to most credibly demonstrate a

product's intended impact (mortality, behavioral disruption) on the target pest and/or crop-pest-other-organism interactions

-- Relaxing crop and pest-specific requirements when registrants have already developed and submitted data on similar crops and pests, unless efficacy problems have been documented in the field or there is a reason to expect lack of efficacy

-- Where possible and appropriate, allowing registrants to use computer generated toxicology models, at least as supplementary data, for biochemical compounds with benign toxicological profiles and/or close similarities to other previously tested compounds

-- Giving priority in seeking and approving Experimental Use Permits, Emergency Exemptions, and Special Local Need registrations to pesticides which display clearly desirable biological and/or ecological properties

Recommendation #29: Create a "Provisional Registration" Option for Safer Pesticides

To speed up the process of getting safer pesticides that contain new active ingredients recently registered by EPA onto the market in California, *we recommend* that DPR seek the authority, either through legislation or administratively, to register safer products on a "provisional" basis, with a waiver of the 30-day posting requirement. Provisional registrations could be granted as a special category of "conditional registration" under Article 4 of the California Food and Agriculture Code. A provisional registration would allow safer pesticides to be used while DPR continues its review of submitted data. The process and criteria governing provisional registrations could be explained in detail through a Policy Letter or rule-making process and would include time frames governing the generation of additional information on a timely basis.

We further *recommend* that DPR and registrants strive to compile and analyze all additional data needed to grant a full registration within three years after a provisional registration is granted. Such additional information would include data to meet California-only requirements -- typically, field data related to worker safety, efficacy, and environmental concerns following widespread commercial use. The granting of provisional registrations would also give DPR sufficient flexibility to take corrective action easily if the need arises.

The trade-off we are suggesting here is that registrants of safer pesticide products with provisional registrations would gain access to the California market earlier but would be required by DPR to develop -- over the first few years of commercial use and under actual field conditions -- more definitive exposure and environmental fate data than DPR would otherwise have. With the

benefit of such information, both DPR and the registrants will be better able to assure that certain products deserve designation as safer pesticides.

Recommendations to waive or delay certain data requirements and to grant provisional registrations earlier in the review process pose a second trade-off: getting new safer pesticide products onto the market quicker than would otherwise be the case but accepting the chance that a few of these products may turn out to be more hazardous than initially thought.

Implementing these recommendations will require DPR (and EPA) scientists to evaluate the properties and potential risks of safer new active ingredients faster, with access to data sets that are less than complete. They will be asked to reach judgements, based on what is known about a new chemical and others like it, regarding whether a given product meets the definition applicable to safer pesticide products. While there will be difficult judgment calls in a few cases, and perhaps even some mistakes, the evidence will in most cases support a clear decision, which may be *not* to designate a product as safer, due to lingering concerns. Also, in any one year, there will be only a few applications for a new active ingredient that meet the criteria governing safer pesticide products. In recent years, about 10 new active ingredients have moved through DPR's system, perhaps one-third of which might have been candidates for the provisional registration we are recommending. Of these, perhaps one or two may pose tough judgement calls.

The importance of this set of policy changes may be more symbolic than practical, at least until research and development priorities shift, resulting in an increased number of biorational control product applications entering the regulatory pipeline. Nevertheless, the overall impact of these recommendations could be decidedly positive to the extent that growers gain access to safer products more quickly and prospective registrants take note of tangible advantages to investments in safer pesticide technology.

It is important to remember that, in general, there will be fewer major surprises arising from unexpected and significant risks associated with provisionally registered safer pesticide products as a class, compared to all pesticides. Moreover, some safer products will work even better than expected and displace a significant volume of materials known to be more hazardous.

Recommendation #30: Expand the Statutory Definition of "Efficacy"

We recommend that the Governor and Legislature enact a Food and Agriculture Code amendment to expand the existing statutory definition of "efficacy" to encompass "efficacy *and* impacts on nontarget species." DPR needs the authority conferred by this definition to be able, when warranted by facts and field experience, to --

- Require manufacturers to conduct studies of impacts on nontarget species -- a requirement which should be imposed only on those products that, under field conditions, are found to be ecologically disruptive and setting off secondary pest problems

- Commission routine monitoring of pesticide resistance, again limited to pesticide products for which there is a reason to be concerned about the emergence of resistance

- Track secondary pest problems associated with certain pesticide use patterns and, if needed, require a field inspection and written recommendation from a pest control advisor with expertise in the affected cropping system

Based on current use patterns and information obtained from such field-based assessments of a pesticide's broader impact on a cropping system, DPR might detect an inadequate margin of ecological safety for certain pesticides. In such cases, DPR and registrants will have a sounder scientific basis to begin designing alternative use patterns that restore minimally acceptable margins of ecological safety. These changes would be in both the registrants' and farmers' interests, since they will help assure that a pesticide product remains effective over time and does not create even more damaging secondary pest problems.

Recommendation #31: Participate in Planning to Set Pest Management Research Priorities

The University of California (UC) recently completed a comprehensive analysis of alternatives to pesticides and reached the conclusion that the use of alternatives in integrated pest management (IPM) systems varies greatly across crops, pests, and regions of the state. *By type of pest*, UC found

> ***Integrated pest management*** (IPM), as defined by the National Coalition on IPM, is a pest management system that anticipates and prevents pests from reaching damaging levels by using all suitable techniques, such as natural enemies, pest resistant plants, cultural management and judicious use of pesticides.

- The widest array of alternatives is available to control insects

- Several mechanical and hand-labor options are available for control of weeds

- Beyond resistant plant varieties, limited options have been developed to control most plant diseases

- The fewest options are available to control soil-borne nematodes, insects, and pathogens, especially when cost factors are taken into account

UC also reported that IPM systems are generally more effective in perennial vineyard and orchard-based systems in contrast to short-season, high-value annual crops such as spinach or radishes, which can be decimated in a few days by insects or disease spores that blow in on the wind. On a positive note, UC found that most prospective and current pests threatening California crops are in fact already suppressed through natural processes, often with little or no intervention.

> "Biointensive IPM" is an IPM system which emphasizes dependence on three primary tactics: biological control, host plant resistance, and cultural management.

The Director of DPR is a member of the UC Center for IPM Research Advisory Committee and does advise that Committee of ways in which recent and pending regulatory actions might affect the viability of current control efforts. But pesticide regulation in general is not sufficiently taken into account within the university system as it applies to pest management research priorities. To overcome this limitation, *we recommend* that DPR and CDFA carry out a joint project, with academic participation, to identify and devise strategies to deal with high risk pesticide use patterns where evidence exists that margins of human health, environmental, or ecological safety are unacceptable. Having this information would enable the University to allocate research resources in response to emerging needs. We ***recommend*** that the joint project be designed to --

- Maintain and update a list of high risk use patterns that are crop-target pest(s)-pesticide combinations
- Seek ways to accelerate the targeting of research effort toward high risk use patterns
- Design and put into place institutional mechanisms to secure funding and initiate needed research
- Accelerate the development of new risk mitigation measures for use in high risk use patterns
- Involve and communicate with the agricultural community regarding efforts and priorities leading to safer systems of pest control -- including growers, researchers, and food processors

Recommendation #32: Design, Test, and License Pest Control *Systems*

Under current law and policy, DPR cannot influence to any great extent the degree to which growers invest time and money to deploy IPM systems as a first line of defense. Instead, DPR's ability to influence progress toward Cal-EPA's goal of encouraging innovative technology to prevent pesticide pollution rests on the program's capacity to get safer new technology registered faster and to restrict the timing, methods, and rates of applications for currently registered products.

Regulators at the state and federal levels are exploring options for encouraging adoption of IPM systems but are finding that little can be done with traditional regulatory tools. In a few cases, EPA and DPR have required at least a minimal set of IPM practices as conditions attached to the granting of §18 Emergency Exemptions and §24(c) Special Local Need labels. Facing the same sort of crop diversity and resistance problems as California, Florida has tried several innovative approaches to incorporation of resistance management practices into the provisions governing §18 and §24(c) labels.

> *"In spite of at least 15 years of registration effort, diflubenzuron has yet to be registered [for use on pears and apples]... in the U.S. and fenoxycarb registration efforts appear destined to the same fate. Consequently, pear and apple [growers] are condemned to continued heavy reliance on a host of older, more dangerous, and unsustainable conventional pesticides. Crop protection of pears and apples in California is a third world enterprise when compared to European production."*
>
> -- California Professional Entomologist

DPR's Rice Herbicide Program has advanced this concept of restricting use of certain pesticides to highly controlled and prescribed circumstances. For 1992, Sacramento's Central Valley RWQCB, based on information provided by DPR, placed the following conditions on discharges of the five rice pesticides of concern:

> The discharge of irrigation return flows containing these pesticides is prohibited ***unless*** the discharger is following a management practice approved by the Board [emphasis added]. To be approved, the practice must be expected to meet specified "performance goals" in all waters designated as freshwater habitat.*

DPR's cooperation with the RWQCB to place conditions on use of restricted pesticides is similar to EPA's groundwater protection strategy (published in October 1991). The core element in EPA's strategy is to add a new provision to pesticide product labels when the agency has determined that certain pesticide products may pose an unacceptable risk to groundwater. The new label provision would include a statement to the effect that:

*Central Valley Regional Water Quality Control Board, Staff Report, 1992.

> This pesticide product may be applied only in accordance with the provisions of an EPA-approved state management plan.

EPA will require that such plans include goals, documentation of statutory authority, monitoring plans, description of the proposed process to develop on-farm management plans, and enforcement mechanisms* -- the same basic elements, in other words, which account for the success of DPR's Rice Herbicide Program.

We recommend that DPR initiate a series of pilot projects to test options for development and licensure of the use of biorational crop protection systems, complete with DPR-specified goals and management practices. The pilot projects should encompass different types of crops, different cropping systems and pest complexes, and alternative crop protection systems. These components should be integrated with concerns for water quality protection, worker safety, restoration of safe and effective methods to control problem pests such as the sweet potato whitefly, and high risk pesticide use patterns such as soil fumigation.

Beginning with pilot projects is important, in part to accelerate the learning process and in part because there is no reason to believe that one model will meet all the needs in the state. ***Therefore,*** *we recommend* that DPR include the following three models among the pilots initially studied:

A. ACADEMIC: Integrate IPM System Practices Called for by the University of California into Pesticide Product Labels and Permit Requirements

There is a little-known provision in the California Code of Regulations granting the Director of DPR the authority to incorporate University of California-recommended IPM practices into pesticide regulation through the permitting process. This authority has not been used. *We recommend* that DPR select a few crops for which UC has developed and published IPM manuals. For these, in selected regions of the state, *we recommend* that DPR invite university pest management specialists, pest control advisors (PCAs) and other crop consultants, growers, and county agricultural commissioners to collaborate in devising product-specific regulations and/or permitting requirements that would be appropriate in light of IPM practices recommended by the University.

We further *recommend* that all academic pilot projects initiated by DPR target specific regions where biointensive IPM systems have been tested and are generally acceptable to growers. The pilot projects should define measurable goals for --

- The rate of adoption of IPM systems

*U.S. Environmental Protection Agency, groundwater strategy document, October 1991,

- Increasing the sophistication and effectiveness of pest control systems

- Overall reductions in pesticide use and risks, expanded margins of safety, pest-related losses in crop quality and quantity, and crop protection costs

Annual reports on the pilot projects should include verification of success in achieving these goals. Once evaluated, if the academic IPM pilot projects demonstrate a high degree of grower acceptance and progress, the University will have reason to redirect additional resources back to IPM research activities -- an area that fared poorly in the 1980s as academic leaders emphasized basic research.

B. EXPERT SYSTEM/PRESCRIPTION USE: Prescribe Use within Biologically-based IPM Systems Designed and Implemented Jointly by Growers and Agricultural Consultants

For high risk crop-pest combinations, the Director may need to impose stricter and more sophisticated risk mitigation measures than the existing range of regulatory options makes practical in terms of compliance and enforceability. ***We*** *recommend* that high risk use patterns be viewed as the ideal context for a pilot project intended to test the viability of using pest control advisors and other agricultural consultants -- in cooperation with their client growers -- to design, deliver, and implement biorational pest management systems.

Instead of trying to use label changes to reduce risks for all pesticides registered on a given crop, ***we further*** *recommend* that the Director of DPR use this pilot project model to establish a set of risk reduction goals, applicable to specific cropping systems in the selected pilot project counties. In those counties and for the selected crops, growers and consultants would choose from two options: (1) continue to use registered products in compliance with all applicable safety precautions; or, (2) seek approval of a crop protection system that meets DPR's pilot project implementation rules, which would include permission to make limited *prescription use* applications of materials not otherwise available for the affected crop -- but only if consistent with the pest management tactics and practices incorporated within an approved pest control system that meets the goals of the pilot project.

DPR would need to clearly explain pilot project goals, rules, and procedures, focusing on the distinctions between options (1) and (2), and the overall goals of the program. The rules would need to address a range of choices for how growers can develop their control systems and would include as options in-house experts and/or growers, when qualified, independent crop consultants, academic experts, and experts working for county agricultural commissioner offices.

This model is designed to test the safety, effectiveness, and affordability of allowing the use of products which would not otherwise be available. In acknowledgement of the need to take greater precautions when there is greater risk, project teams should include, when possible, *independent* advisors or consultants who have no financial interests in the sale or application of potentially

An ***independent agricultural consultant*** is an individual who provides advice and recommendations to client growers regarding the design and/or day-to-day management of agronomic and pest control systems, and who receives no direct or indirect financial gain from the sale or application of any product or input he or she recommends.

high risk pesticides. Such individuals should be held responsible for prescribing and overseeing the use of high risk pesticides, including adherence to the provisions of crop protection system plans developed by the project team and approved by DPR. As in the case of the academic model, *we recommend* that DPR require the pilot project teams to articulate their goals for reducing pesticide use and risks and a proposed methodology for measuring, monitoring, and reporting their performance.

C. JOINT POWERS AUTHORITY (JPA): Establish a Joint Powers Authority to License DPR-approved Pest Control Sys terns

A joint powers authority (JPA) is an institutional hybrid. California Government Code $6500 *et.seq.* authorizes two or more public agencies representing multiple levels of government to band together for any legitimate purpose as described in their written agreement specifying the powers which the parties agree to delegate to the JPA. Intent language in the statute indicates that JPAs were created to meet needs and purposes that are outside any existing public agency's mission and standard operating procedures. JPAs do not receive General Fund support except through contracts to provide specified services at negotiated rates. The definition of a public agency eligible to enter into a joint powers agreement includes "any...public corporation" [Government Code §6500].

We recommend that the Governor and Legislature enact legislation to establish a joint powers authority to license DPR-approved pest control systems. ***We further*** *recommend* that the JPA be organized as a nonprofit public benefit corporation and governed by a board of directors appointed by the member agencies. The members of this JPA should include -- but not be limited to -- DPR, boards of supervisors of participating counties, county agricultural commissioners, incorporated agricultural commodity groups, scientific associations, and participating campuses of the University of California.

The proposed JPA would serve three primary functions, all of which eventually would be supported by fees paid directly to the JPA on a fee-for-service basis:

- First, the JPA would license crop-specific pest control systems created by teams of growers, consultants, PCAs, and other experts to meet the standards and requirements for licensure established by DPR. These specifications should include minimally acceptable risk reduction and pollution prevention goals. The licensing function would entail review and evaluation of the soundness of each pest control system proposal and its conformance with licensing standards.

- Second, the JPA would sell or support consulting services and applied research efforts in a variety of areas. For example, the JPA could provide pest monitoring and management advice on an hourly fee basis to growers whose farm size would make retaining the services of private, independent crop consultants with comparable expertise prohibitively expensive. It could sell and calibrate sophisticated mixing-loading and application equipment or periodically monitor pesticide resistance levels. The JPA might also sell marketing assistance to licensees, to help them find other growers who would benefit from the crop protection systems they have licensed.

- Third, the JPA could assist in expanding both the pesticide tool kit and availability of nonchemical control options by seeking §24(c) labels, assisting in the generation of data needed to support minor use pesticides, and contracting with private firms to supply nonproprietary biorational products or for the raising of beneficial insects.

Over time, the JPA would gain the capacity to carry out special studies and other efforts to improve the effectiveness of IPM systems. Experienced staff would be able to recognize and solve new problems on a timely basis and help growers comply with all applicable safety precautions and reporting requirements. These enhancements would, in turn, improve the quality and value of the services offered by the JPA, as well as warrant the confidence that DPR placed in the safety, effectiveness, and affordability of pest control systems advanced through and licensed by the JPA.

Conceivably, the JPA model may evolve into a unique institutional arrangement for ensuring the availability of pest management services and systems that are both profitable for growers and consistent with environmental protection and regulatory goals. In the best of all possible worlds, the JPA would become a self-sustaining public agency capable of encouraging and supporting professional and technical investments in the design and delivery of biorational crop protection systems.

Recommendation #33: Use Regulation to Encourage Innovation

Whether for experimental purposes in designing pilot projects or to advance the safety, effectiveness, and affordability of pest control systems and products through traditional regulation, we *recommend* that DPR use its regulatory powers and knowledge about pest control challenges creatively to encourage innovation and careful attention to the circumstances that can influence the need for and effectiveness and safety of a given pesticide application.

Initially focusing on high risk pesticide use patterns, we *recommend* that DPR seek ways to encourage or require that --

- Proven pesticide resistance management strategies are specified and adhered to

- Field-level analytical and diagnostic methodologies needed to implement bio-intensive IPM are developed, refined, and adapted where needed -- including economic thresholds, ways to monitor levels of resistance, proper identification of pest species, models to predict the impact of weather and water management on pest development and population levels, and methods to track the interactions of target pests, other species, and pesticides

- Licensed PCAs with the appropriate expertise make determinations that target pest populations are above the threshold level for economically significant damage before prescribing high risk pesticide products

- Certified experts, including appropriately skilled PCAs, prescribe the timing and method of application to assure maximum efficacy with minimal risk

- Application operations are supervised by a licensed PCA or PCO, or other certified individual responsible for assuring that the provisions of the written prescription are followed and are in accord with applicable safety precautions

- When warranted by concerns about efficacy, current pesticide use reports are augmented by a brief evaluation by the PCA within one week after application (or other appropriate interval) describing the degree of control achieved, noting any secondary pest problems observed, and predicting whether any additional control measures will be needed and, if so, what and when

Moreover, we *recommend* that DPR and CDFA jointly develop, with assistance from the University of California, a data base on the extent of use of safer systems, the practices and materials used within them, levels of control achieved, reliability of control, factors affecting control, and economic consequences. This data base could evolve into a valuable tool for DPR, CDFA, and Cooperative Extension and would be an important resource for manufacturers trying to determine how to improve existing pest control systems. It could also provide graduate students and academic researchers unique opportunities to carry out research on the factors determining the performance of safer pest control systems.

Recommendation #34: Establish a Cooperative Agreement with the University of California, Riverside to Monitor Resistance in the State's Major Pest Species

Scientists agree that *preventing* resistance is the least costly and disruptive means of resistance management, because it is generally easier to preserve susceptible gene pools than to restore them and easier to avoid stimulating resistance than to discover and develop new pesticides that work through a novel and target-specific physiological mode of action. Preventing resistance, therefore, should be a strategic component of DPR's efforts to prevent pollution, because resistance

often leads to a decision to make more frequent pesticide applications or to add new pesticides with undesirable characteristics into a control program, or both,

DPR and EPA currently administer certain policies which are counterproductive to resistance management. For example, both agencies stipulate that no alternatives to a particular product are available before they will grant a state-level registration such as an Emergency Exemption or §24(c) SLN label. This requirement is counterproductive, as argued in Chapter II, because safer pest control systems are made possible by the availability of alternatives. The *absence* of options can make the use of a single pesticide or method unreliable. As the pesticide tool kit gets smaller throughout the 1990s, information on the presence and rates of change in pesticide resistance will become progressively more vital to DPR.

We recommend that DPR -- perhaps jointly with EPA -- establish a cooperative agreement with the University of California, Riverside to systematically monitor the presence of resistance in the state's major pest species. This monitoring effort would draw upon information maintained and continuously updated by the UC/Riverside Department of Entomology in its global data base on documented instances of pesticide resistance.

We further recommend that DPR prepare quarterly reports for distribution on a subscription basis. These reports would summarize new developments in the degree of resistance observed in pests throughout the state and predict when specified pesticide use patterns might no longer be efficacious in particular regions. DPR's resistance management bulletins would report documented cases of resistance to pesticides applied commercially first in other countries where affected cropping systems and pests resemble those in California, as well as suspected cases of resistance in California.

In reporting suspected cases of resistance, DPR's bulletin would ask readers in the field to forward any information they have that either confirms or disproves specific suspicions. In this way, the geographic regions affected could be more accurately delineated. With the benefit of such information, registrants, growers, and DPR would be alerted to the need to design and target adoption of resistance management plans in various parts of the state.

EPA also has a major role to play in combating resistance. *We suggest* that EPA require registrants to include a resistance management statement on the labels of products for which there is documented evidence of resistance. The label statement might include tactics to prevent resistance or instructions on how to obtain specific information and instructions for managing resistance in a given area. To support EPA and registrant efforts, *we further suggest* that Cooperative Extension and land grant universities provide advice on resistance management tactics, tailored to each region and reflecting up-to-date information on the level of resistance, so that farmers and consultants have a better chance to devise *truly preventative* resistance management plans.

Appendices

Appendix 1

PESTICIDE REGISTRATION STUDY ADVISORY COMMITTEE

In an effort to enhance the range of expertise and ideas considered over the course of the study, an 1 l-member advisory committee was formed. The role of the Advisory Committee was to present ideas and aid in the evaluation of issues; identify sources of information that should be taken into account; suggest specific DPR policies or procedures that should be assessed; help select case studies or examples of certain program strengths or weaknesses; and to act as a sounding board.

Throughout the project, the contributions of the Advisory Committee, both as a group and through individual conversations, were extensive and valuable. In accord with the study charter, the Advisory Committee was not asked, and has not formally approved the report. Members played no role in the writing of the report, nor bear responsibility for its content.

The Advisory Committee met as a group three times: March 5, May 7, and July 7,1992. All three meetings were held at DPR in Sacramento. In addition, several smaller meetings with one or a few members of the committee were held over the course of the study. The following individuals served as members of the Advisory Committee:

Brian Baker, Ph.D.
Technical Program Coordinator
California Certified Organic Farmers

Steve Balling, Ph.D.
Manager, Pest Management Program
Del Monte Foods

Tim Butler
Sales Representative
DuPont Agricultural Products

Wendy Gelernter, Ph.D.
Director of Product Development
Mycogen Corporation

Ron Gilman,President
California Agricultural Commissioners Association

Ron Hanson
Manager, State Regulatory Affairs/Western Region
Rhone Poulenc

Ed Kurtz
Agricultural Consultant
Iceberg Lettuce Research Advisory Board
American Dehydrated Onion & Garlic Association
Western Growers Association
Grower-Shipper Vegetable Association, Central Coast

Lawrie Mott, Senior Scientist
Jennifer Curtis, Research Associate
Natural Resources Defense Council, Inc. (NRDC)

George Soares
Kahn Soares & Conway

Susan Wayland, Deputy Director
Anne Lindsay, Director, Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency

Patrick Weddle, President
Weddle, Hansen & Associates, Inc.

DPR Liaison:
Tobi Jones, Ph.D.
Chief, Pesticide Registration Branch
Department of Pesticide Regulation

Appendix 2

REGISTRANT SURVEY RESULTS

The unique experiences, evaluations, and insights of the regulated community comprise an important element in the accurate appraisal of strengths and weaknesses in DPR's pesticide registration program. In order to collect this information, Benbrook Consulting Services (BCS), in cooperation with the Western Agricultural Chemicals Association (WACA), worked to design and develop a survey that would provide a structured vehicle for the industry to describe and document their interactions with DPR in California and with EPA at the federal level.

At a discussion with WACA members who attended a WACA Registration Committee meeting on April 2, 1992, the group decided to prepare two survey forms: one for basic registrants and a second for formulators, me-too manufacturers, and specialty chemical companies. The two surveys targeted companies, or divisions within larger companies, that engage in different registration activities and therefore have different experiences with the regulatory process. The *Basic Registrants Questionnaire* was distributed by WACA, and the *Pesticide Product Registrants Questionnaire* was distributed by WACA, the Chemical Specialty Manufacturers Association (CSMA), and the Chemical Producers and Distributors Association (CPDA).

The responses from registrants provided valuable data and insights regarding the policies and procedures of DPR and regarding the interactions and linkages between DPR and EPA. The results were among several sources of information utilized in shaping the analysis for the report, reaching conclusions, and deciding upon the recommendations. Benbrook Consulting Services is grateful for the cooperation of the trade associations and the participation of their members.

The survey for basic registrants included six qualitative questions; the seventh question asked for quantitative comparisons of DPR and EPA. The survey for me-too registrants and formulators contained three questions about the results of registration actions sought since 1990, plus one question that sought a quantitative comparison of DPR and EPA. This Appendix contains a summary of the main recurring themes in the responses from both surveys, followed by the text of each question as it appeared in the survey form and a summary of responses.

SUMMARY OF SURVEY RESPONSES

Basic registrant respondents stressed several major points repeatedly. The most often repeated point -- frequently stated adamantly -- concerned DPR's policy of reviewing data which already have been reviewed and approved by EPA. Registrants strongly believe state resources should be spent strengthening those aspects of EPA's review that do not sufficiently address use patterns and exposure scenarios in California, particularly worker-safety risk assessments and determination of environmental risks. Registrants are also nearly unanimous in their desire to see an end to the requirement of efficacy data, especially in those cases where a product's effectiveness

(or lack thereof) is quickly and unambiguously visible and obvious -- as with most agricultural pesticides -- and for those products containing an active ingredient for which efficacy data have already been submitted and approved.

> *'lt seems tremendously duplicative for DPR scientists to review the very same studies/information that EPA has reviewed and accepted, especially in the areas of Toxicology Analytical Chemistry, Environmental Fate, and Residue Chemistry. This is especially true for a new active ingredient or a product under re-registration. "*
>
> -- Registrant

Said one registrant: "DPR's insistence on inclusion of efficacy data causes a delay in our submission of a regulatory package to California, and causes us to delete certain pest/crop combinations from our California label that appear on the federal label. In particular, California's requirement of efficacy data to support use of our product on EACH CROP that the insect occurs on is quite onerous, and unnecessary."

Another problem repeatedly cited by survey respondents is the requirement for a printer's proof of the EPA-approved label. California is the only state with this policy. Registrants feel it is time-consuming and expensive to produce -- $10,000 to $25,000 -- and often risky. If DPR successfully challenges EPA's approval of the type face or location of statements, then the registrant must supply another printer's proof. One registrant said: "The Department expects final printed labeling to be prepared . . . even though we have no guarantee it will be accepted. To prepare final printed labeling in anticipation of acceptance is a financial gamble for registrants."

Several respondents expressed strong interest in a concurrent review process by at least some of the review stations within DPR. "Some of the review areas have different work loads and concurrent reviews would allow those with adequate time to complete their review in a timely fashion instead of waiting their turn," wrote one registrant, echoing comments from others. Advocates of concurrent review recognize that sequential review is sometimes necessary, as when Worker Health and Safety needs input from Medical Toxicology before it can make an evaluation. However, there are many minor label amendments for which sequential review is not warranted (for example, product chemistry and medical toxicology).

In general, respondents to the survey were not at a loss for words when it comes to DPR's process for review of label amendments. Requests to reestablish the decision making authority of the registration specialists as to whether a change is substantive or not were numerous -- along with broadening the definition of nonsubstantive. However, the policy change registrants *most* want to see is a limit to the review of data to those which are relevant to the label amendment application. Registrants contend that any request for a label amendment can serve as an invitation to review all the data on file. After telling the story of a toxicity category change which was accepted by EPA, but not by DPR, one registrant wrote: "The peculiar aspect of this action is that the data found unacceptable were not the data submitted to support the action; those data were found acceptable. But rather, this action provided an opportunity to 'dig into' other aspects of the product and request

additional data when it had not been required by EPA. DPR should limit their review to the data relevant to the amendment, unless a hazard is indicated."

Finally, registrants are eager to see a change in the 30-day posting policy. Registrants want the posting period to begin simultaneously with the final stages of review. "The benefit derived from th[e existing requirement] does not seem to be supported by the surmised administrative costs of typing, tracking, publishing and mailing of weekly notices. However, if the 30-day posting requirement cannot be avoided, it would be advantageous to allow the posting as soon as possible, and not necessarily wait until all the paperwork is 'in hand' if there have been positive reviews." Registrants cite economic losses from the sometimes lengthy delays that result from DPR's stringent registration process and believe this is one policy change that could increase efficiency without any compromise in human health, environmental safety, or, as one company noted, "the democratic process."

BASIC REGISTRANTS QUESTIONNAIRE

I. *What does DPR do right? What encouraging signs do you see in the evolution of California pesticide regulatory programs and policies?*

Eight Responses: Several registrants expressed preference for DPR's system of one registration specialist per company. However, two respondents noted the potential for unfortunate infusion of personal opinion into the review process that can come with the discretion allowed to registration specialists. DPR won compliments for leadership in worker health and safety, superior enforcement efforts, and pesticide residue monitoring. For example, half the respondents praised DPR personnel:

- Staff members are helpful and provide good communication to us
- DPR administrative personnel are much more accessible than EPA

Timeliness was another point of praise:

- DPR is good at meeting registration deadlines
- DPR is almost always faster than EPA in reviewing data
- DPR approves nonsubstantive label changes rather quickly, compared to EPA

On the other hand, several noted that the Department seems to be slowing down: "Recently, we have experienced significant delays in obtaining simple label amendments that have affected our ability to market several key products and, in one case, we missed the entire season because of such a delay," said one registrant.

More than half the respondents praised DPR's thorough review of data, although nearly every respondent questioned whether a thorough review of all data is needed, especially for new active ingredients or a product under reregistration where the data have been recently reviewed and

approved by EPA. "DPR's program should complement EPA's program, not duplicate it. They should divert resources away from duplicative efforts and focus more on hazard characterization, risk assessment, and unique California conditions." Another respondent simply said, "DPR spends too much time rechecking EPA's work and not enough time analyzing what the data mean for California growers and consumers."

2. *Please identify and provide information about any promising 'safer" pesticides (biologicals, semiochemicals, low-toxicity products) that your company has considered developing and registering, but ultimately decided not to. What were the reasons for not pursuing registrations? Were DPR/California registration requirements a significant/moderate/minor factor in your decision?*

> *"There is a need for a provision to allow medium size testing (i.e. >10A) . . . Development decisions are difficult to make without adequate broad-scale testing, especially for biologicals, since they perform differently under various environmental conditions."*
>
> -- Registrant

Four Responses: Three respondents believe DPR registration requirements are a significant barrier to the development and registration of "safer" pesticides. Two specifically mentioned the inhibitive role of the requirements for an emergency use permit (EUP). After relating the tale of one failed Bt product registration, another respondent echoed the same sentiment, saying "[i]f there really is an interest in promoting biological approaches to pest control, a nurturing regulatory environment must be created wherein entrepreneurial ideas can be given a chance to be evaluated before their financial support is exhausted."

In general, the responses indicated a wariness toward the state and federal regulatory environment for biologicals. Two respondents noted "inconsistency, confusion, and disagreement" within and between DPR and EPA. "Products that need California registration to make them successful have come under scrutiny because of the uncertainty of the California regulatory system," said one registrant.

> *"We have several products safer for the environment and the applicator for which we have not sought California registration. The cost and time to develop duplicative data and a lack of kegulatory common sense' have kept us out of that market and placed California growers at a disadvantage."*
>
> -- Registrant

All three respondents who agreed DPR requirements are a barrier specifically noted the negative role of efficacy data, be it for safer or conventional pesticides. One registrant listed twelve crops -- including citrus, grapes, and apples -- that appear on the federal label but which cannot be treated in California with one of that company's biological products due to a lack of efficacy data. Another registrant reported that his company had to provide completely new efficacy data for a color change of a cleaning product: "The only change was that the product went from a bluish to a

greenish color and [DPR] required new efficacy data -- as if the green would work any less good than the blue -- after we spent $8 million dollars on product development."

3. *How can the system within which, or through which, pesticides are used be altered to improve the overall safety, efjcacy, andprofitability of crop protection efforts at the field level? To combat resistance and secondary pest problems?*

Six Responses: Half the respondents said the answer to these problems lies in a redirection of DPR resources -- away from duplicative reviews and toward a program that, in practice and theory, supports a systems-oriented approach to pest control. "The most prudent mechanism to prevent pest resistance and/or secondary pest outbreaks is to maintain the highest number of viable pest control measures . . . [Yet,] regulatory agencies resist registering additional compounds for the same pest thus, in effect, thwarting IPM efforts. This is especially true in the role of Section 18 and 24(c) registrations."

Two of the six respondents strongly urged a relaxation of requirements for an EUP, noting "testing and development of new products is the key to the evolution of successful strategies . . . The ten-acre limit is extremely prohibitive in the conduct of efficacy, phytotoxicity, and resistance management experimentation where several locations would be desirable, as well as the use of commercial scale equipment."

"Merely expedited review could see millions in profitability at the field level" said one respondent. Continuing this theme, other respondents suggested allowing simultaneous submission of data to DPR and EPA and ensuring "equity of requirements" between the two agencies. Two respondents dismissed the question by saying resistance management, profitability, and efficacy are not the role of the regulatory agency.

4. *When regulators reach a judgement that a certain crop use of apesticideposes risks too great to accept, a risk mitigation alternative to cancellation/denial of registration could entail tighter controls over the conditions of use -- timing, number/rates of applications, controls over volume applied over multiple seasons, use in conjunction with IPM systems, greater precision/control over applications, etc. Given current tools and enforcement capabilities, regulators decide in some instances that technically feasible risk mitigation strategies are nonetheless unenforceable or otherwise impractical. Do you favor creating new mechanisms or tools to increase the confidence of regulators in such sophisticated risk mitigation strategies? If so, what sort of mechanisms, requirements, orpolicies do you thinkshould be explored?*

Five Responses: "This is the cutting edge in decision making for pesticides, but risk mitigation has a long, proven track record in other industries. Understanding the reality in the field is critical for enforceable mitigation measures. This has historically been a problem with EPA."

Another said, "California's enforcement is generally knowledgeable, stringent and dependable, which is a good starting place." These two respondents strongly favored risk mitigation as an alternative to cancellation, but both stressed the need to follow through any change in application methods or use patterns with appropriate training and enforcement, incentives, and penalties.

Two respondents replied negatively, saying increased reliance on risk mitigation is not the answer. "Any more risk mitigation would be impractical and unenforceable," said one.

The fifth respondent said the answer to increasing the number of pest control tools and confidence in regulators is to encourage research by both industry and universities, especially in the areas of application methods, exposure reduction, and pesticide alternatives. "Industry often resists testing in California, or planning a cooperative research with scientists there because of the regulatory scrutiny this testing commands. Any policy changes to encourage research or loosen the permitting requirements for testing would be beneficial to the development of safer alternative strategies."

5. *For new active ingredients registeredfor the first time in Caltfornia since January 1, 1987 by your company (or a company you now own), or for which you have sought but not yet received registrations, please provide the following information [NOTE: By "new active ingredient, 1 we mean a never before registered active ingredient that represents new chemistry; by "registeredfor the first time, "we mean the granting of the first California label corresponding to an EPAlFIFRA Section 3 label; approximate locations and dates will suffice in response to parts (a) through (c) below]:*

   a. *Where and when was the active ingredient's currently registeredpesticidal activity discovered?*

   Five Responses:

   1. Japan, 1974
   2. United States, 1984
   3. United States, 1983
   4. United States, 1985
   5. Germany, 1982

   b. *OPTIONAL Where and when were the majority of the field-scale studies carried out that produced data in support of registration of the active ingredient for current California crop uses?*

   Five Responses:

   1. California, 1976-1992, Japan, 1976- 1980, England 1976-1978
   2. Ornamental turf herbicide: no crop uses. Studies conducted in California and Arizona.
   3. Field scale work in California

4. Field trials in Florida
5. Termiticide: no crop uses

c. *OPTIONAL In which county and when were the first full registrations granted, leading to significant commercial use? Was the active ingredient used in other states before California, for the same crop use (i.e. pears in California versus pears in Oregon) ?*

Five Responses:

1. It was registered in the United States first, in 1989, and by 1990 it was registered in all states and Washington D.C., except California.
2. The first registration was granted in Japan in April, 199 1. EPA registration was granted in June, 199 1. The only registration achieved in California was for a two-year EUP Section 5.
3. Japan first registered the product. EPA approved a Section 3 registration in 1989, and several other states had it before California.
4. First registered in the United States.
5. First registered in the United States in 1982. It was a business decision to delay marketing until 1986/early1987. By 1986, registered in 2 states. In 1987, 44 more states had it, and by 1988, another 2 states. Still pending in California.

*d. Please provide the following dates: submission of tolerance petitions (s) to federal EPA covering major Caltfornia crop uses; final approval **of** the EPA tolerances and registrations corresponding to the tolerancepetition covering California crop uses; submission **of** corresponding registration applications to Caltfornia; confirmation from California that the applications were complete and entering review; approval or denial **of** registration application in California and, date when commercial sale/use could begin?*

Five Responses:

1. (non-crop use)

Submitted to EPA:	01/89
Approved by EPA:	12/89
Submitted to DPR:	07/90
Denied by DPR:	08/91

2. (non-crop use)

Submission to EPA:	01/89
Approved by EPA:	06//91
Submitted to DPR:	07/91
DPR request for additional info:	08/91
Requested data sent:	10/91
Registration pending as of:	05/92

3. (crop use)

Submission of tolerance EPA:	02/87
Tolerance approved by EPA:	06/89
CA EUP Submission:	01/87
CA EUP granted:	04/87
Submission to DPR:	01/88
Confirmed received by DPR:	04/88
Notified data pkg incomplete:	05/88
New application:	11/88
Registration approved by DPR:	04/89

4. (crop use)

EUP submitted to EPA:	11/88
EUP approved by EPA:	02/90
EUP appl & full data to DPR:	04/90
EUP approved by DPR:	03/91
Section 3 application to EPA:	08/89
Tolerance exemption from EPA:	06/91
Federal registration granted:	06/91
Submitted to DPR:	07/91
Registration approved by DPR:	03/92

5. (non-crop use)

Submitted to EPA:	10/81
Approved by EPA:	07/82
Submitted to DPR:	10/87
Notified rec'd and incomplete:	08/88
Application denied by DPR:	11/88
Resubmitted application:	02/89
Notified complete and going into review:	06/89
Registration denied:	03/91

e. In the course ofpursuing the California registration actions relative to (d) above:

- *Was the data package submitted to DPR returned because it lacked required data? If yes, please describe each such instance.*
- *Was the data package ever returned, or was additional data requested in order to address a potential adverse effect? If yes, please describe each such instance (i.e. dates, nature of concern, requested data).*

Five Responses:

1. Regisration denied for outstanding AB 2021 data
2. DPR requested additional data on 8/29/911;sent in 10/17/91.This data request was not specifically to address adverse effects.
3. Data requested and package returned for lack of data on worker exposure, drift, and non-target movement. We do not believe this was needed to address potential adverse effects.
4. Yes, additional data requested to prove efficacy on each crop, and storage stability data. Additional delay because DPR required us to add a dermal sensitization warning to the label above and beyond the warning dictated by EPA.
5. Yes, data requested four times and package returned twice. Request for additional acute toxicology data on 7/7/88 and g/2/88; package returned 12/16/88.Resubmitted 6/30/89; 9/7/89 request for additional worker exposure data (sent 9/13/89); 12/12/89request for supporting data for worker exposure studies (sent 12/22/89);registration denied 3/91.

f. *By crop use, or for non-crop uses, what is the number of --*

- *Uses for the active ingredient for which the federal Section 3 label now has "California Only" restrictions? What is the nature of the restrictions?*
- *Other states with state-spectfic restrictions on the label?*

Five Responses:

1. N/A (no state restrictions)
2. N/A (registration pending)
3. N/A (no state restrictions)
4. There are 12 crops that appear on the federal label of this biological product but not California for lack of efficacy data.
5. N/A (registration pending)

6. *Please list active ingredients or product uses that have been taken off the market since January 1, 1987 for which your company (or a company you now own) once held California registrations, and state the reason/basis for the removal of the product from the market. Was the decision driven by regulatory concern over risks, by the cost of meeting regulatory program data requirements, because of a lack of market demand, or a combination of these factors?*

Seven Responses:

1. No active ingredients have been canceled, but four products have been dropped in California: three due to the cost of California data requirements -- specifically, AB 2021 and SB 950 -- and the fourth due to a lack of market.
2. One herbicide active ingredient was voluntarily canceled by our company in 1991 due to the cost of compliance with AB 2021.
3. We have dropped eight active ingredients from California due to the cost of meeting California data requirements. All these formulations are being sold in other states.
4. We have dropped six active ingredients: two at the state level only and four at the federal level. The two state cancellations were the result of business decisions -- the cost of data generation was not warranted by the market demand in any state except Florida. Most of the federal cancellations were the result of the cost of EPA reregistration data call-ins. Two products were replaced with different formulations.
5. One active ingredient was suspended by regulatory actions of DPR. It is used widely across the country. The regulatory decision was driven by the use of default assumptions of peak concentrations and equivocal chronic toxicity data and a hasty finding of unacceptable risk.
6. No actives canceled.
7. No actives canceled.

7. *Perspective is needed on the relative or comparative efficiency and scientific justification for DPR and EPA actions, policies, and programs. Please provide a numerical answer to each of the following questions.*

RATING SCALE: I, 2, 3

I: Score a "I" if you feel EPA does a better job or is otherwise preferable to DPR in the specific area or issue raised in the question.

2: Score a "2" if you feel there is no significant difference between DPR and EPA.

3: Score a '3" tf you feel DPR does a better job in the area, in contrast to EPA.

a. *Eflciency **of** actions moving through the process /.e., number **of** times things get lost or drop out **of** sight, unexplained delays, errors, etc]*

AVG	1s	2s	3s
2.62	0	5	8

b. *Predictability ofprocess, clarity and adherence to stated procedures and policies*

AVG	1s	2s	3s
2.17	2	6	4

Both respondents who gave scores of " 1" explained that they never knew when data approved by EPA would be unacceptable to DPR. One said: "We don't know what their decision rules are for toxicology data. We know they aren't the same as EPA's, but we don't know what they are."

One respondent who did not give a numerical score explained that there had been several policy and judgement reversals from DPR in the last year. "As you know OEHHA is now more actively involved as a peer reviewer for certain mixer, loader, applicator studies. It has been our experience that they will make a more conservative interpretation than Worker Health and Safety, which has resulted in mixed signals from these two groups. Another respondent echoed this sentiment: "The internal political positioning between OEHHA and DPR is such that assessment of risk and allowed pesticide use are affected by default assumptions which drive ultra-conservative decisions."

c. *Quality of scientific review, soundness **of** questions raised, and justt$cations **for** requests **for** further information. Please identiJj, spectjic studies/examples where you feel particularly unfounded and damaging differences exist in the way DPR and EPA evaluate studies and carry out risk assessments.*

AVG	1s	2s	3s
1.67	6	4	2

One respondent admitted giving a score of "1" despite believing DPR does a more thorough scientific review, but said DPR's degree of evaluation is not justified: "DPR follows the strict letter of the law and makes no decisions based on the spirit of the law." Another said: "DPR reviewers

are more thorough in their review of environmental fate and toxicology data . . . however, they are less flexible than EPA regarding the strict adherence to the guidelines, regardless of whether the minor deviations have any relevance to the scientific usefulness of the data."

A third respondent said: "The comparison should not be between DPR and EPA, but between states. The question is how much safer are the people of California than the people of Texas or Florida because of the presence of another review?"

d, Relative to risk mitigation (please rate each category below separately):

-- *Science-base and "reasonableness" of proposed risk mitigation actions proposed and/or taken*

AVG	1s	2s	3s
2.00	4	3	4

-- *EfJiciency and efectiveness of theprocess through which risk mitigation actions were shaped [i.e. without judging the validity of the actions, what about the process through which they evolve]*

AVG	1s	2s	3s
2.30	1	5	4

e. Effectiveness of actions taken to:

-- *Reduce the chances of resistance becoming a problem*

AVG	1s	2s	3s
2.08	1	9	2

-- *Promote adoption of IPMsystems*

AVC	Is	2s	3s
2.10	1	7	*2*

-- *Protect groundwater quality*

AVG	1s	2s	3s
2.50	1	*3*	*6*

-- *Reduce worker exposure and risk*

AVG	1s	2s	3s
2.40	1	*4*	*5*

-- *Minimize adverse impacts on wildlife*

AVG	1s	2s	3s
1.80	*2*	*8*	*0*

PESTICIDE PRODUCT REGISTRANT SURVEY

*I. For registration actions sought or completed by your company since January 1, 1990, please provide the following information. (If your company sought more than 6 actions within each category, please provide the total number **of** such actions since January I, 1990, and the following information on at least 6 such actions, including the first three completed in 1990 and the first 3 completed in 1991.) For registration actions discussed below, please give the following information:*

*a. Types **of** Actions*	*Responses*
New Product (previously CA registered active ingredient):	*30*
Subregistration:	16
Formulation Change:	*22*
Label Amendment:	*74*
Change in Ownership/Firm Name:	*6*

*b. Indicate, where possible, whether action was **for:***	
Consumer Product:	*86*
Agricultural Product:	14
Institutional/Industrial:	*48*
Structural:	0

c. *How long did it take for the EPA to process the accompanying federal registration action?*

d. How long did it take DPR to act on the request?

	EPA : DPR (months)
New Product:	17.2 : 7.5
Subregistration	
Requiring EPA review:	8.25: 3.7
EPA notification only:	N/A : 2.9
Formulation:	6.6 : 3.8
Label Amendment:	8.0 : 3.0
Change in Owner:	5.2 : 0.9

e. *Was the action requested approved by DPR:*

	Approved: Denied : No Response
New Products:	22 : 8 : 0
Subregistration:	8 : 6 : 2
Formulation change:	7 : 5 : 10
Label Amendment	
Initially:	16 : 32 : 26
Finally:	38 : 10 : 26
Change in Owner:	5 : o : 0

f: IMPORTANT: If DPR approval was denied what was the reason for denial?

The most common reason for delay was incomplete data packages -- especially lack of efficacy data -- or inadequate data provided by the basic registrant. Six respondents reported denials based on clerical errors, including two typographical errors, two lost letters of authorization from the basic registrant, and two lost active ingredient data files. Most of the denied label amendments were the result of DPR objections to label language or lack of printer proof label.

g. Was additional data or information required before the action was approved by DPR?

All respondents answered yes.

Was the information required to resolve the denial, described in (f) above?

All respondents answered yes.

Was this data or information previously required by the EPA?

All respondents answered no. In the cases of incomplete or inadequate data, five respondents reported it was the result of DPR's objection to bridging data. Ten applicants were asked for additional acute toxicology data, seven for additional skin irritation data, two for additional eye irritation data, one for additional product chemistry data. Seven required an additional letter from the basic registrant/holder of information on the active ingredient. Also, eight applications were denied for lack of efficacy data (data not required by EPA). Finally, approximately 10 percent of the respondents to Question 1 listed registration actions for adjuvants, which are not required by EPA.

*h. Was the registration action the result **of** specijic compliance mandates (e.g., CA VOC regulations, EPA mandates) ?*

Yes: 22 were the result of EPA mandates.

No: approximately 30 were not the result of any regulatory mandates.

*i. Did DPR regulatory actions and requirements result in your company deciding to not pursue, drop, or not seek labels in California? If yes, **for** which pesticide-crop combinations, or non-crop uses, and in which other states do you sell the product **for** the use pattern foregone in California?*

Yes: eight labels were dropped in California. Of these, three were due to cost of AB 2021 and SB 950 and efficacy and registered in all other states and DC; four were dropped due to cost of efficacy data alone and remain registered in all other states and DC; one was lost because of the cost of efficacy data and dropped in all other states due to the importance of the California market.

No: 11 respondents are still pursuing everything in California.

No response: 11

*2. Please listproducts or uses taken off themarket in California since 1987. Were any cancellations due (initially) to California regulatory concerns or issues (either DPR issues or other California agencies)? Were both **California** andfederal EPA labels dropped?*

Seven respondents had dropped products or uses in California:

1. All products with toxicology data generated prior to 1985 are not being reregistered in California. All continue to be sold in all other states.
2. 38 products were canceled in California, only 18 of which were canceled at the federal level. All of the California only cancellations were the result of AB 2021 and SB 950 data costs.
3. Nine insecticides and three disinfectants were dropped due to lack of market demand. One herbicide and one microbicide voluntarily canceled due to EPA reregistration costs. One disinfectant dropped due to a DPR requirement for California-based field testing.

4. Three consumer products dropped due to additional California data requirements. One herbicide dropped due to reclassification as restricted material in California and several other states. Registration dropped in all those states, but EPA label is still valid and the product is sold in about ten states.
5. Two products dropped due to cost of California data and lack of market, and one due to cost of EPA reregistration.
6. Four canceled by EPA regulatory action due to risk concerns.
7. Three products dropped because higher annual registration fees at EPA and DPR made them unwise to market.

No dropped products or uses: 3
No response: 4

3. *Please identify and if possible provide information about any promising "safer" pesticides -- that is, biologicals, semiochemicals, low-toxicity products -- that your company has considered developing, but ultimately decided not to. Please explain the reasoning for not pursuing the new chemical.*
None/not applicable: 3
No response: 13

4. *Perspective is needed on the relative or comparative efficiency and scientific justification of DPR and EPA actions, policies, and programs. Please provide a numerical answer to each of the following questions (questions a. through f.):*
RATING SCALE: 1, 2, 3
1: Score a "1" if you feel EPA does a betterjob or is otherwise preferable to DPR in the specific area or issue raised in the question.
2: Score a "2" if you feel there is no significant difference between DPR and EPA.
3: Score a "3" if you feel DPR does a betterjob in the are, in contrast to EPA.

a. Efficiency of actions moving through the process [i.e., number of times things get lost or drop our of sight, unexplained delays, errors, etc.]

AVG	1s	2s	3s
2.33	*3*	*6*	*9*

b. *Predictability ofprocess, clarity and adherence to stated procedures and policies*

AVG	1s	2s	3s
2.11	3	10	5

c. *Quality of scientific review, soundness of questions raised, and justification for requests for further information. Please provide a separate I, 2, or 3 score for each of the following categories of studies/reviews.*

	AVG	1s	2s	3s
Efficacy	2.00	5	7	5
Chemistry	1.72	7	9	2
Toxicology	1.56	9	8	1
Label Review	1.83	8	5	5
Other Evals.	1.94	3	12	2

d. *Relative to risk mitigation (rate each one):*

-- *Science-base and "reasonableness" of proposed risk mitigation actions proposed and/or taken*

AVG	1s	2s	3s
1.43	10	2	2

-- *Efficiency and effectiveness of the process through which risk mitigation actions are shaped [i.e. without judging the validity of the actions, what about the process through which they evolve]*

AVG	1s	2s	3s
2.93	5	5	4

e. *Effectiveness of actions taken to [rate each category below separately; if your company has no experience with a given category because of your product line, respond with "N/A"] --*

-- *Reduce the chances of resistance becoming a problem*

AVG	1s	2s	3s	N/A
2.25	0	6	2	10

-- *Promote adoption of IPM systems*

AVG	1s	2s	3s	N/A
2.17	1	3	2	12

-- *Protect groundwater quality*

AVG	1s	2s	3s	N/A
2.40	1	4	5	8

-- *Protect air quality*

AVG	1s	2s	3s	N/A
2.27	1	6	4	7

-- *Reduce worker/consumer exposure and risk*

AVG	1s	2s	3s	N/A
2.42	1	5	6	6

-- *Minimize adverse impacts on wildlife*

AVG	1s	2s	3s	N/A
2.09	1	8	2	7

One obviously frustrated registrant returned the survey unanswered with a letter that reflected strong sentiments expressed by other respondents in their cover letters and survey forms. An excerpt from this letter follows:

> Every state, except California, is a pleasure to deal with. The rest of the states act like states. California thinks it is a country of its own. California DPR is a business determinant in and of itself. The rules, regulations and taxes imposed by California are, at times, ludicrous . . . DPR has no horse sense, that is for sure... The US/EPA is stringent enough; the DPR is a class bully that will eventually get its due. The State of California will probably file bankruptcy the same day the insects devour it. Thank the DPR. Move to Texas before it's too late.

Appendix 3

AGRICULTURE IN CALIFORNIA

California agriculture is the highest value and most diverse in the nation. The state's gross agricultural income exceeds $18 billion annually, with no livestock or crop commodity accounting for more than 13.5 percent of the total. Sales of more than 25 crops and commodities exceed $200 million each in most years, or slightly more than 1 percent each. By contrast, corn and soybean sales account for about 50 percent of gross farm income in Illinois, cattle and wheat for over 40 percent in North Dakota. Only Florida approaches the diversity of California's agriculture.

Even for major field crops such as cotton and, in vegetables, tomatoes, California production systems and climatic conditions are unique, as are pest species and crop-pest interactions. Moreover, California grows major proportions of several fruit and vegetable crops: 93.9 percent of the nation's apricots; 99.9 percent of almonds, dates, figs, and olives; and 100 percent of kiwifruit, clingstone peaches, pistachios, and prunes (dried basis). Hence, most of the nation's problems encountered in controlling pests in these crops are unique to California.

Table 3.1: Sales, Acreage, State Rank, and Share of U.S. Production of California's Top Five Vegetable and Top Five Fruit/Nut Crops -- 1990

	Market Sales ($000s)	Harvested Acres (000s)	Rank Among All CA Commodities	CA Share of US Production
Vegetables				
Lettuce	$682,700	162.2	8	76.2%
Tomatoes				
Processing	617,001	310.0	9	89.9
Fresh	273,258	38.0	16	28.9
Broccoli	244,695	97.5	17	91.0
carrots	180,184	56.1	25	59.5
Fruits and Nuts				
Grapes	$1,499,712	639.0	3	91.6%
Almonds	591,560	411.0	10	99.9
Oranges	562,443	175.1	11	38.6
Strawberries	431,366	20.0	13	78.7
Avocados	239,400	75.0	18	75.5

SOURCE: California Department of Food and Agriculture, *California Agriculture: Statistical Review 1990.*

TOP TEN CALIFORNIA COMMODITIES

In 1990, the ten commodities ranking highest in production among all commodities grown in California were as follows:

1. Milk and cream 20.9 billion pounds	$2.6 billion
2. Cattle and calves 2.7 billion pounds	$1.7 billion
3. Grapes (all types) 5.2 million tons	$1.5 billion
4. Cotton (lint and seed) 1.8 million tons	$1.2 billion
5. Nursery products	$1 .O billion
6. Hay, alfalfa 8.3 million tons	$905.5 million
7. Flowers, foliage	$900 million
8. Lettuce 2.8 million tons	$682.7 million
9. Tomatoes (processing) 9.3 million tons	$6 17 million
10. Almonds (shelled) 330,000 tons	$591.6 million

Appendix 4

STATUTORY AUTHORITY FOR CALIFORNIA'S PESTICIDE REGULATORY PROGRAM

A series of state laws enacted over the last eight decades has made California's pesticide regulatory program both extensive and institutionally unique. Many of DPR's strengths can be traced directly to its statutory authority. Many of its problems arise from difficulties encountered in trying to keep up with legislative mandates that strive to push DPR faster than resources will allow it to move, or into areas of great scientific uncertainty.

This appendix describes first the basic statutes and standards governing pesticide regulation in California. Three major bills passed in the 1980s greatly expanded DPR's scope of work; these also are described. Last, new legislative proposals under consideration are previewed to give a sense of the next generation of new laws DPR may be required to enact.

STATUTORY FRAMEWORK

Despite the scope of California's pesticide regulatory laws, the majority of the state's regulations and enforcement authorities are shaped and governed by federal law and regulations promulgated by the U.S. Environmental Protection Agency (EPA). DPR's basic mission as a state enforcement agency is to carry out certain functions and authorities delegated to it by EPA which, in turn, is carrying out federal legislative mandates assigned to it through provisions in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The program's statutory foundation provides DPR a clear mandate to assure that pesticide use in the state poses as little risk as possible to the general public, farmworkers, and the state's environment and wildlife. The basic decision rule is simple: DPR may approve a pesticide registration application if it is convinced that there is an adequate margin of safety to assure no adverse effects, assuming the pesticide is used in accordance with its label and any additional permitting requirements DPR might impose under certain circumstances. The key phrases used to set the health standard DPR must adhere to include:

- *[T]he director shall endeavor to eliminate from use in the state any economic poison which endangers the agricultural or non-agricultural environment, is not beneficial for the purposes for which it is sold, or is misrepresented.* Food and Agriculture Code, Chapter 2, Article 4, Section 12824

The Director may cancel the registration of an economic poison which has demonstrated:

- *[S]erious uncontrollable adverse effects,* or *the use of which is of less public value or greater detriment to the environment than the benefit received by its use.* Food and Agriculture Code, Chapter 2, Article 4, Section 12825

EPA, on the other hand, is charged by FIFRA to register a pesticide upon determining that:

- *[I]ts composition is such as to warrant the proposed claims for it; its labelling and other material required to be submitted comply with the requirements of FIFRA; it will perform its intended function without unreasonable adverse effects on the environment; and, when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.* FIFRA, Section 3(c)(5), 7 USC 136a

Similarly, the EPA Administrator may cancel the registration of a pesticide if the Administrator finds that:

- *[W]hen used in accordance with widespread and commonly recognizedpractice, [it] generally causes unreasonable adverse effects on the environment.* FIFRA, Section 6(b), 7 USC 136d (FIFRA defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." FIFRA, Section 2(bb), 7 USC 136)

EXPANDING DPR's ROLE

Beginning in the early 1970s, the California Legislature began a series of actions intended to provide DPR with new resources and tools to carry out responsibilities delegated to DPR by EPA. In addition, out of frustration over the pace of progress in filling data gaps and dealing with high risk pesticides at the federal level, the California Legislature has on many occasions compelled DPR to move ahead of EPA, collecting scientific data needed to carry out cutting-edge human health or environmental risk assessments. The Legislature has also compelled DPR to put in place risk mitigation measures, when considered necessary, that may be stricter or more comprehensive than those brought about by federal law -- for example, encompassing some new type of risk or prospective route of exposure. In the mid-1980s, the California Legislature markedly broadened DPR's mandate with three milestone bills:

- *Birth Defect Prevention* Act (Chapter 669/Statutes of 1984 [SB 950]) required DPR to fill existing chronic toxicity data gaps on active ingredients, using EPA's data requirements and testing protocols, under a timetable that has proven to be both faster than EPA's under the federal reregistration program and faster than DPR has been able to manage.

- ***Pesticide Contamination Prevention*** Act (Chapter 1298/Statutes of 1985 [AB 2021]) compelled DPR to implement a comprehensive data call-in and review process focusing on groundwater contamination. Six years after passage of AB 2021, EPA published in the Federal Register a strategy that vests the states with the task of protecting groundwater and calls upon them to carry out assessments of leachability that are possible only with the sorts of data DPR has now requested from pesticide registrants.

- ***Dietary Risk Assessment*** (Chapter 1200/Statutes of 1989 [AB 2161]): mandated that DPR, in cooperation with the State Department of Health Services, conduct an assessment of dietary risks associated with the consumption of produce and processed food treated with pesticides. The bill also requires DPR to monitor processed foods for pesticide residues and other contaminants, and establishes a requirement for full reporting of all pesticides used. This bill passed during public debate on Proposition 128, the so-called "Big Green" initiative that would have led to the cancellation of more than 20 cancer-causing pesticides. Chapter 1200 was crafted and moved through the Legislature with industry support in the hope that its passage would lessen the chances of Big Green's passage by the voters.

Legislative gridlock at the federal level and EPA's slow pace in completing special reviews during most of the 1980s no doubt played a role in motivating the California Legislature to pass the first two bills. The third bill was passed in an effort to reduce the perceived need for Proposition 128, which was ultimately defeated in the citizens' referendum.

The legislative enhancement of DPR's regulatory program has not pleased everyone. Some farmers and much of the chemical industry believe the California Legislature has gone too far and created a regulatory monster. Environmentalists, on the other hand, often argue that DPR is *too* reluctant to use its risk reduction tools. While clearly a strength overall, DPR's statutory framework does contain loose ends and a few counterproductive, vague, or conflicting provisions.

Given that both the state Legislature and the U.S. Congress are moving toward passage of reform bills, an opportunity may arise to correct statutory deficiencies. But consensus on positive solutions may be fleeting since views seem to be diverging on certain fundamental issues, such as the basic health standard governing regulation and the role and definition of benefits. In any event, DPR needs to pay close attention to developments in the legislative branch of government, with the hope of fixing recognized problems and, at a minimum, preventing the application of new constraints to wise decision making.

PENDING LEGISLATIVE PROPOSALS

DPR entered the 1990s with a full range of duties and a new institutional home within a new agency (Cal-EPA). Change seems constant. Currently, for example, seven new bills are in various stages of development in the California Legislature, some of which are likely to pass eventually in one form or another. In addition, federal legislation reforming both FIFRA and the provisions governing the setting of tolerances in the Food, Drug, and Cosmetic Act (FDCA) are expected to pass in the first session of the new Congress.

The following bills were considered during the 1992 legislative session, and most are expected to be reintroduced next year:

- ***AB** 2786: Pest Control Operations* Introduced by Assembly Member Rusty Areias, Chairman of the Assembly Committee on Agriculture

AB 2786 addresses the rules governing the state's licensure of pest control advisors (PCAs). It would prohibit licensed PCAs from receiving income in the form of bonuses or commissions tied directly to the volume of pesticide product sales resulting from their recommendations to grower-clients. Strongly opposed by industry, the bill failed on April 6, 1992 to pass out of committee (short one vote). Chairman Areias has promised to be back next year with an improved version.

- ***SB** 520: Acutes* Introduced by Senator Nicholas Petris

SB 520 addresses the release of extremely toxic chemicals into the environment. This "acutes bill" does not specify either pesticides or DPR but, nevertheless, is designed to force DPR to suspend the use of acutely toxic pesticides by establishing maximum allowable levels for acute toxicity. Chemicals "applied by air or by pressure driven spray applicators" that exceed the following triggers would be subject to suspension --

-- Inhalation -- an LD 50 of 0.2 mg/liter or less at one hour or less (doses at which one-half of the exposed test animals die)
-- Q&1-- an LD 50 of 50 mg/kg or less
-- Dermal -- an LD 50 of 200 mg/kg

- ***SB** 1794: Cholinesterase Poisoning* Introduced by Senator Gary Hart

SB 1794 addresses cholinesterase poisoning risks by tightening reporting requirements applicable to physicians who treat patients with pesticide-induced inhibition of chlorinesterase levels, the common biomedical indicator of organophosphate or carbamate pesticide exposure. The bill also calls for the improvement and standardization of techniques to quantify the extent of impact on normal chlorinesterase function and certification of laboratories carrying out such assays.

- *AB 2728: Nonvehicular Sources **of** Air Contaminants* Introduced by Assembly Member Sally Tanner

AB 2728 would place jurisdiction for pesticides found in air under the California Air Resources Board (ARB) by including pesticides in the definition of "nonvehicular sources of air contaminants." The bill would require the ARB to adopt reduction and control plans. If passed, this bill would create significant bureaucratic and turf challenges between DPR and the ARB.

- AB 2787: ***Economic Poisons*** Introduced by Assembly Member Areias

AB 2787 would prohibit the manufacture, delivery, and sale of economic poisons for which the registration has been suspended, thereby prohibiting a pesticide product from clearing the channels of trade. It also requires the directors of DPR and CDFA to "review and comment, as specified, upon certain regulations proposed to be adopted by federal EPA relating to agricultural pesticide containers."

- ***AB** 3395: Active Ingredients* Introduced by Assembly Member Tom Hayden

AB 3395 would extend authority the Director now has to suspend the registration of products to 400 additional active ingredients that are formulated with the 200 most widely used and "dangerous" active ingredients covered by SB 950.

- ***SB** 926: Nonagricultural Use of Pesticides* Introduced by Senator Petris

SB 926 would require the Director of DPR to cancel by 1993 any "school use" pesticide (defined as "any economic poison registered for nonagricultural uses") that contains any active or inert ingredient known to cause cancer or known to cause reproductive harm, and to cancel by 1995 any "high hazard" pesticide (defined as any pesticide identified by US EPA as a possible human carcinogen or classified by FDA as a demonstrated or potential high health hazard), unless the product label is changed to prohibit its use in schools or day care facilities. Pesticides to control human contagious diseases are exempt.

CALIFORNIA-ONLY DATA REQUIREMENTS

In response to a series of bills over the years, DPR has promulgated 17 categories of California-only data requirements. These requirements (described in Title 3, Article 3, Sections 6176-6192 of the California Administrative Code) are applied selectively to products that may pose certain types of risk. In some cases, data generated to meet EPA requirements fully or partially satisfy California-only requirements. The 17 categories of California-only data requirements are:

1. ***Dennal absorption*** -- required for each pesticide product containing an active ingredient with acute dermal toxicity of LD 50 of 2,000 or less milligrams/kg of body weight in 24-hour period

2. ***Dennal or inhalation*** -- data required for products in toxicity category one or two which are expected to result in respiratory or dermal exposure during mixing, loading or application

3. ***Antidote*** -- protocol supported by data for the practical treatment of poisoning and other injury cases

4. ***Acute toxicity*** -- data on the formulated product for any spray adjuvant exempt from an EPA tolerance

5. ***Metabolic pathway and mode of action*** -- rodenticide data suitable for extrapolation to people describing metabolic pathways and mode of action in animal models;

6. ***Foliar and soil residue*** -- data for any pesticide product to which field workers may be substantially exposed

7. ***Field reentry intervals*** -- data used to establish safe field reentry intervals (ensuring a no-effect level is present on foliage and soil when workers reenter a treated field) which are derived from dermal absorption, inhalation, and dermal/oral-response studies, in conjunction with foliar and soil dissipation data

8. ***Indoor exposure*** -- data for pesticide products used in houses, institutions, or other buildings

9. ***Residue analysis methods*** -- practical analytical methods for determining residues of each active ingredient and any metabolites (for food crop pesticides, analytical methods must allow determination of the residue on each crop within a continuous 24-hour period)

10. ***Residue*** -- data obtained under California or similar environmental use conditions, with consideration of differences in plants, soils, climatic conditions, and application techniques

11. ***Efficacy*** -- data to be obtained under California or similar environmental use conditions

12. ***Acute and chronic toxicity to bees*** -- data indicating a product's acute and chronic toxicity to bees for any product likely to contact commercial apiaries or pollinating bees

13. ***Viscosity*** -- data for any liquid pesticide for agricultural use which carries the word "DANGER" on the label

14. ***Adverse effects*** -- data for pesticides with a new crop use concerning any adverse effect of the product on pest management systems for that crop

15. ***Inerts*** -- chronic toxicity data on any product containing an inert ingredient not specifically exempted from this requirement by the director

16. ***Evaporative emissions*** -- data on evaporative emissions of volatile organic compounds in a pesticide which may interfere with the attainment and maintenance of ambient air quality standards

17. ***Special requests*** -- data requested by the director on the following product characteristics: pesticide drift, phytotoxicity, environmental effects, analytical andenvironmental chemistry, effect from mixing two or more products in combination, or contaminants in the pesticide product

Appendix 5

REREGISTRATION PROCESSES AND PROGRESS IN FILLING DATA GAPS

Both Cal-EPA's Department of Pesticide Regulation (DPR) and the federal Environmental Protection Agency (EPA) are in the midst of implementing laws calling for more complete product testing and the reregistration of pesticide products. These laws and processes will result in re-evaluation of pesticide risks and benefits for all products initially granted regulatory approval prior to human health and environmental safety standards incorporated into pesticide regulatory legislation during the 1970s.

DPR, under provisions of California's Birth Defects Prevention Act of 1984 (SB 950), must require pesticide registrants who seek access to the California market to meet all of the same data requirements specified for the registration of a new active ingredient, or for reregistration by EPA. Indeed, in many cases DPR has required registrants to fill EPA data requirements *before* EPA has done so.

SB 9.50 The Birth Defects Prevention Act provides, for example, that registrants must submit studies done in compliance with EPA's 1982 guidelines for 10 chronic toxicity data requirements. California law requires DPR to *suspend* registrations of products for which data gaps are not filled within the time frames prescribed in the state statute. DPR instructed registrants to adhere to EPA's data requirements and testing protocols. This decision did not remove all uncertainty, however, and both EPA and DPR have had to decide whether to issue data call-ins in many cases where the need for, or validity of, the request was difficult to ascertain. Both DPR and EPA have had to spend much time and resources determining:

- Pesticides for which all 10 core toxicology studies must be completed, and by when
- Pesticides for which studies already on file could fill a data gap, either fully or as supplemental information
- For each of the 10 core data requirements, which additional studies are needed to satisfy each requirement and how those studies must be designed and conducted

These are important decisions, with significant consequences for both registrants and regulators. Certain studies routinely required under state and federal reregistration laws cost in excess of $1 million for the registrants to conduct and take weeks of effort for EPA and/or DPR scientists to review.

Given the limits of current scientific knowledge, certain emerging issues -- such as how to set the dosage ranges in an animal experiment, or how high the maximum dose must be -- have to be agreed upon rather than scientifically determined. Disagreements between registrants and

regulators take time and cause delay. Occasionally, disagreements between DPR and EPA scientists over the interpretation of EPA data requirements and testing protocols creates a wedge that further complicates discussions with registrants and further delays regulatory decisions.

PROGRESS REPORT ON CALIFORNIA'S REREGISTRATION PROCESS

Reregistration began in California with DPR's announcement to pesticide registrants in a 1988 notice that EPA's 10 core toxicological data requirements must be fulfilled in order for DPR to grant or continue pesticide product registrations. Of 200 active ingredients affected by the notice, DPR determined by the fall of 1988 that 22 were no longer registered and that DPR had all required data in hand for 14. For the remaining 168 active ingredients, DPR determined at that time that:

- For 42 active ingredients, all required data had been received but not reviewed
- For 38 active ingredients, registrants had committed to initiate all required studies
- For 43 active ingredients, DPR and registrants were still debating whether data on file were adequate or whether a given requirement should apply
- For 41 active ingredients, registrants had yet to commit to fill acknowledged data gaps

Data developed by registrants and submitted to erase DPR's core toxicology data gaps on these 168 active ingredients will also be submitted to EPA and will, in nearly all cases, also fulfill the data requirements at the federal level.

A measure of the progress made in getting untested pesticides off the market and assuring that all data gaps will soon be filled is evident in Table 5.1.

Table 5.1: Progress in Filling Core Toxicological Data Gaps for 200 Priority Active Ingredients under SB 950: September 1988 to May 1992

	Number of Active Ingredients 10/88	5/92
Regulatory Status		
Current registrations	178	151
No current registrations	22	49*
Total cases	200	200
Status of Data Gaps		
All requirements met	14	44
Studies in hand, not all reviewed	42	42
Commitment made to do all studies	38	39
Discussion ongoing regarding required studies	43	14
No commitment to conduct required studies	41	12
Total cases	178	151
Cases needing additional data	122	65
Number of Studies Needed for 65 Active Ingredients	**Total Cases/Total Commitments**	
1 or 2 studies	40 /	29
3 to 7 studies	21 /	10
8 to 10 studies	4 /	0
Total number of studies needed to meet IO core requirements	1,780 /	1,510
Studies needed to fill data gaps		
Total number/percent of total	183 /	12%
Commitments to do/% of total required	95 /	6%

* Includes four active ingredients for which all registrations have been suspended

SOURCES: September 1, 1988 status report in letter to Honorable Nicholas Petris and internal DPR records. February 1992 data from internal DPR records.

Significant progress is clearly being made in filling the requirement for 1,780 core toxicological studies that were called for in the state reregistration process. As of September 1988, the 10 core data requirements had been met for 56, or 3 1 percent, of the 178 active ingredients with current registrations. By February 1992, the 10 core toxicological studies were completed and submitted to DPR for 86 active ingredients, or 57 percent the total 15 1 actives with current registrations (down from the original 200) -- nearly double the percent in 1988.

Mixed Progress Despite solid progress, the reregistration process may be entering troubled waters on three counts. First, DPR has to decide how to implement the "drop dead" deferral provisions passed in 1991 amendments to the original 1984 act. Second, over the next few years, DPR faces the task of *evaluating* all the new data that have been submitted in response to its requests. Finally, some of the studies reviewed first by DPR will show heightened risk -- periodically forcing DPR to move ahead of EPA, either in crafting risk mitigation measures or withdrawing registration approval.

Indeed, DPR may have to suspend registrations of several hundred pesticide products in order to comply with current law. A January 19, 1992 press release from Cal-EPA/DPR announced that the next step in reregistration, due to registrants' failure to comply with the requirements of reregistration, would be DPR's suspension of 3,000 pesticide products (containing 57 active ingredients) by June 1992.

Some of the active ingredients on the prospective suspension list are used in major, widely applied agricultural and home use products. DPR is clearly moving ahead with reregistration, but the calendar-driven, one-product-at-a-time focus of the program may place DPR in the position of having to suspend a product that the Department feels is actually safer and more effective than other products that will continue to be available. The reregistration program is designed to assure that pesticides on the market are fully tested; it also *aspires* to assure that products available to farmers are safe. DPR needs to proceed so that efforts to achieve one goal do not set back progress toward the other.

Regulator's Discretion The 1991 amendments (SB 550) to California's Birth Defects Prevention Act of 1984 authorized the Director to alter the state's reregistration timetable in two ways, either by extending the time to develop required data or deferring suspension actions.

- **Extension** Extensions of time to fill data gaps may be granted if (1) eight of the required studies have been submitted and the remaining required studies were initiated by January 15, 1992 [unless the delay in submission arose from a dialogue over protocols or other technical issues with DPR staff toxicologists]; or (2) the registrant/data generator has taken appropriate steps to meet the requirements of the Act. [DPR's California Notice 91-23, 3 1 December 1991]

- **Deferred suspension** The Director may defer suspension of products with data gaps if suspension would (1) cause substantial economic hardship to the users; or (2) be more detrimental to the environment than continued use; or (3) result in significant risk to public health. If suspensions are deferred for any of these reasons, the Director may impose a fine of up to $1,000 per day.

These amendments provide DPR a mechanism needed to balance the risks and benefits associated with allowing use of certain pesticides that might be subject to suspension. Before DPR can exercise this authority consistently, however, it must define the standards upon which its decisions will be based. What is the difference, for example, between "appropriate" and "inappropriate" steps a registrant may have taken to fill data gaps? On what basis will an economic hardship be judged "substantial?" What makes a threat to the public health "significant?" Judging from past experience, DPR can expect criticism from one or more quarters regardless of how it chooses to interpret and apply these terms.

Until DPR provides policy guidance regarding how it will make such judgements, registrants will craft their own interpretations and standards and then bring forth data they believe satisfy the standards. DPR will have to contend with the validity and acceptability of the standards registrants have set for themselves. It may be difficult in these circumstances for DPR to treat registrants equitably, leaving the Department open to a challenge that one regulatory action is inconsistent with actions taken in other similar cases. DPR would then face the burden of articulating, after the fact, the logic and criteria upon which a set of decisions had been made.

Fines As noted earlier, for pesticides granted a deferral of suspension, the Director is to levy a fine of up to $1,000 per day per active ingredient. Since filling chronic toxicology data gaps requires studies that take up to four years to design, conduct, and evaluate, the fine could exceed $1 million -- about one-half the cost of a two-year chronic feeding study.

The maximum fine should be reserved for cases in which the Director concludes that registrants seeking the deferral worked in bad faith to delay initiating needed studies. If another registrant, or a grower group, steps forward and seeks time to fill remaining data gaps, they should be granted an opportunity to do so without facing a fine. Also, in setting fines, the Director should keep in mind that the causes for delay in keeping up with the original SB 950 time frames for filling data gaps arose in many cases from joint efforts by registrants, DPR, and EPA to resolve legitimate issues at the margins of scientific knowledge.

EPA'S DATA CALL-IN AND REREGISTRATION PROGRAM EFFORTS

EPA also is in the midst of a massive data call-in effort, receiving as many as 10,000 studies per month. Extensive data call-ins issued by EPA are an integral part of the accelerated reregistration program mandated in 1988 amendments to FIFRA. Obtaining solid data is an essential first step that enables regulators to reach science-based judgements regarding levels of risk and the adequacy of risk mitigation measures.

While conceptually straightforward, filling data gaps is in practice an enormously complex and resource-intensive job -- both for the regulators and the registrants, who are required to pay for the new studies. Determinations must be made which requirements apply to a given pesticide and crop use. Regulators must decide whether any studies currently on file meet current requirements and, when data gaps are partially filled, which additional data might be needed to address outstanding issues. Indeed, specialists in DPR's Medical Toxicology Branch sometimes have to spend nearly as much time to determine whether a set of older studies meets a given requirement as it takes for them to review a new study that would fill the requirement.

Some people argue that DPR should revisit its policy of re-reviewing all or most basic toxicology data packages submitted to EPA (see, for example, responses to the registrant survey, summarized in Appendix 2). They argue that the resource-intensive tasks of reviewing the validity and checking the statistical findings and interpretations of core toxicology studies should be EPA's job, leading to risk characterization judgements as well as quantitative methods for translating exposure estimates into risk estimates. DPR's tasks would then be to develop accurate exposure profiles under California conditions and to complete quantitative risk assessments on the basis of such exposure estimates.

DPR scientists and decision-makers appreciate this argument, but point to several cases where acceptance of EPA reviews and risk quantification decisions -- which tend to focus on concerns relative to chronic dietary exposure risks -- would have missed key insights relevant to evaluating, for example, the risk of ocular effects among farmworkers under California conditions. For this reason, it is a complex task to decide which studies need to be reviewed and for which sorts of effects.

Appendix 6

IMPROVING THE SCIENCE BASE FOR REGULATION

Special studies initiated and carried out by DPR, or in cooperation with DPR scientists, often lead to changes in both state and federal labels. In other cases, special studies establish the scientific basis for special, county-specific guidance documents on the ways a pesticide must be used in order to assure an adequate margin of safety. Necessary risk mitigation measures are then required and enforced through California's permitting process.

In many cases, exposure and risk assessment methods developed or refined in California have been adopted subsequently by EPA and other states. In addition, data compiled during special DPR field investigations have often played a key role in refining EPA's assessment of risks and benefits, in some cases leading the federal agency to alter its regulatory course.

DPR has made significant contributions to understanding the following elements of pesticide risk assessment:

Exposure Assessment Methods

- Worker safety exposure assessment methods
- Indoor air exposure assessment methods and risk assessment models

Risk Characterization: Human

- Effectiveness of closed-system chemicalmixing, loading, and application equipment in reducing worker exposure
- Application of acute toxicity and other tests in determining possible dermal, ocular, and other risks to farmworkers

Risk Characterization: Wildlife

- Methods to measure avian toxicity under field conditions

Risk Mitigation Options

- Methodologies for establishing field re-entry and pre-harvest intervals to assure an adequate margin of safety for pickers and other farmworkers
- Cultural methods to reduce triazine surface water run-off in orchards

Impact of Irrigation on Pesticide Environmental Fate

- Impact of irrigation management and scheduling on the levels of pesticide residues flowing into surface waters

Risks of a Negative Regulatory Decision A lot can ride on a regulator's decision regarding which effects observed in an animal study are "compound-related." These decisions often hinge on

complex statistical and toxicological issues, such as whether an observed adverse effect in a given organ system is somehow relevant to a similar, or possibly a different, human health effect.

Experts often disagree in making these judgements. EPA has sponsored dozens of research projects each year, convened multiple scientific advisory panels to review its regulatory applications of toxicological science, commissioned several National Academy of Sciences studies on risk assessment techniques and related issues, and adhered to complex scientific peer review procedures. Nevertheless, due to scientific uncertainty and the cost of compiling sufficiently broad sets of data, there is no way to guarantee that regulators will always make the right decision.

Conventional and Expedited Evaluation Procedures An article in *Risk Analysis Magazine* by Dr. Carl Cranor, a member of California's Proposition 65 Scientific Advisory panel, states: "[I]t takes an agency such as the California Environmental Protection Agency from 0.5 to 5 person years per potency assessment using conventional risk assessment procedures.... These are time, human resource, and cost intensive."

An analysis of 75 suspect carcinogens implicated by Proposition 65 was undertaken by Dr. Cranor, Dr. Lauren Zeise, and other staff scientists working for Cal-EPA's Office of Environmental Health Hazard Assessment (OEHHA). This group's findings are relevant to the choices DPR must make in deciding how to deal with the enormous body of data it will receive over the next five years. Cranor and colleagues assessed the degree of concordance between conventional and expedited procedures to evaluate a chemical's cancer potency. Results of the study are reported in the above mentioned article and in OEHAA's report, *Expedited Cancer Potency Values and Proposed Regulatory Levels for Certain Proposition 65 Carcinogens* (April 1992).

Conventional methods take 0.5 to five person years per chemical; the expedited procedures often take less than one person month per chemical. The differences between the conventional and expedited procedures are: (1) the expedited procedure relies on cancer dose response data already reviewed and contained in an extensive data base managed by scientists at Berkeley's Lawrence Livermore Laboratory; and (2) the multi-stage model for extrapolating risk from animal experiments to humans is used as a default assumption, allowing no consideration or adjustments for pharmacokinetic factors. According to the 1992 OEHAA report:

> The concordance between the expedited and conventional results is excellent, particularly considering the substantially different resources and time required by the two approaches.

Even more significantly, the analysis found that the differences between the conventional and expedited potency estimates were no greater than the differences in potency estimates calculated by U.S. EPA and Cal-EPA when both agencies used conventional methods on the same chemicals. Cranor concludes by saying:

> For all comparisons between conventional and expedited approximation procedures, the total social costs of expedited methods are always lower than conventional approaches across a wide range of values assigned for individual regulatory mistakes of underregulation and overregulation. ... It is better to evaluate a larger universe of known carcinogens somewhat less intensively for each substance than to evaluate a small proportion of the same universe very carefully and ignore the rest. ... Efficiency is not ordinarily considered a virtue of scientific investigation, but in regulatory contexts it may be as important a consideration as accuracy in the assessment and identification of toxic substances.

Chemicals that emerge from an expedited evaluation process as more worrisome than once thought would become candidates for interim risk reduction measures, as well as more intensive risk assessments. The results of this expedited review, once available, could prove valuable in meeting another pressing need: hastening the pace at which registration packages now move through the Medical Toxicology Branch. Expedited procedures for health effects in addition to cancer will be needed to help DPR identify which active ingredients and pesticide products to focus on, so that risk mitigation needs can be determined and acted upon sooner.

Appendix 7

STATE REGISTRATION ACTIONS

California agriculture is considered one of the most diverse in the world. Over 250 crops and livestock commodities are grown here, in a wide range of geographic, soil, and weather conditions. This variation produces many specific pest-crop-regional problems for which no federally registered products offer relief on a consistent and affordable basis. This is increasingly true in the wake of federal reregistration. To date, 25,000 pesticide product labels have been dropped as a result of the reregistration process, and the number of currently registered active ingredients has fallen from 1,153 to 640. California growers have been hit especially hard by regulatory actions and, as a result, are likely to become more reliant on the special state issued registrations allowed under Sections 18 and 24(c) of FIFRA.

SECTION 18: EMERGENCY EXEMPTION

Section 18 of FIFRA [40 CFR, Part 166] outlines the criteria under which emergency exemptions from Section 3 requirements for registration may be allowed. EPA believes an emergency condition exists only when the situation is urgent, non-routine, and meets all three of the following conditions:

1. No effective registered pesticides are available
2. No feasible alternative control practices are available
3. The situation
   - (a) involves the introduction of a new pest; or
   - (b) will present significant risks to human health; or
   - (c) will present significant risks to threatened or endangered species, beneficial organisms, or the environment; or
   - (d) will present significant economic loss due to an outbreak or an expected outbreak of a pest or a change in plant growth or development caused by unusual environmental conditions where such change can be rectified by the use of a pesticide

Although Section 18s require EPA approval, about half of the requests received by DPR are not forwarded to EPA because they are denied by DPR for not meeting the criteria or for lack of required data. In California, DPR reviews the requests for chemistry, efficacy, phytotoxicity, fish and wildlife, and worker safety. In those few instances where the product is not already registered for some other use in California, toxicology data must be reviewed and found acceptable. DPR also requires a letter of authorization from the basic registrant granting permission to register the product for this specific use. Failure to secure registrant authorization is a common reason for denial. A table of DPR's Section 18 activity over the last eight years appears on the next page.

Table 7.1: Section 18 Emergency Exemptions, California Department of Pesticide Regulation

	Number of Requests Made to DPR	Number of Requests Denied by DPR	Number of Requests Sent to EPA	Number of Requests Denied by EPA	Number of Section 18s Issued
1992"	34	17	17	**0**	17
1991	30	8	22	**0**	22
1990	39	18	21	**3**	21
1989	36	11	25	**1**	24
1988	37	13	24	**3**	21
1987	35	8	27	**3**	24
1986	36	8	29""	**1**	27
1985	21	3	18	**1**	17

* 1992 numbers reflect Section 18 actions through June 30, 1992. DPR reports that most requests for Section 18s occur early in the year, so the numbers reported above will closely resemble year-end figures.

** One 1986 request sent to EPA was withdrawn by DPR when a tolerance was established.

OTHER NOTES: The number of denials by DPR and EPA are tabulated only for the written requests received. The numbers do not reflect those denials made verbally (many of which required research time, alternatives analysis and other efforts by DPR staff).

SOURCES: DPR staff and tracking reports

California has the highest level of Section 18 activity in the country. Florida's is second highest. To provide perspective on the role of Section 18s in the nation's two states most heavily involved in the production of fruits and vegetables, Benbrook Consulting Services sought data from the Florida Department of Agricultural and Consumer Services on its 1990-199 1 Section 18 activity.

Table 7.2: Section 18 Emergency Exemptions, Florida Department of Agriculture and Consumer Services (FDACS)

Number of:	Requests Made to FDACS	Requests Denied by FDACS	Requests Sent to EPA	Requests Denied by EPA	Section 18s Issued
1991	23	3	20	2	**18***
1990	21	1	20	2	**17****

* Two applications were withdrawn by the applicant and one received Section 3 registration while under EPA review.
** One request was withdrawn by the applicant.
SOURCE: Florida Department of Agriculture and Consumer Services

Emerging EPA Section 18 Policies In March 1992, EPA issued a report entitled *Emergency Exemptions under Section 18 of the Federal Insecticide Fungicide and Rodenticide Act: Guidance for State and Federal Agencies.* The introduction stated that "the document summarized the Agency's positions and policies regarding those issues reviewed by the Section 18 work group.... It is meant to clarify certain parts of the existing regulations and to serve as additional guidance." Section XI, "Innovative Approaches to Repeat Section 18 Problems," discusses a new initiative in the Office of Pesticide Programs (OPP) to develop innovative and nontraditional approaches to achieve the Agency's environmental objectives.

> As part of this strategy, OPP is considering new opportunities under the Section 18 process that will allow the Agency to effectively deal with pest emergencies and reduce risk. In general, the Agency would like to identify pest problems that consistently result in emergency exemption requests, and work with the states and affected growers to develop ways to address these problems using new and/or little known technologies.

One such innovative effort is underway with the control of the Colorado potato beetle (CPB) on potatoes in the northeast. In 1984, the first of a series of controversial repeat Section 18 Emergency Exemptions for the use of cryolite on potatoes to control the CPB were issued to the states of New York and Rhode Island. In 1986, the registrant (Pennwalt Corporations, which later changed its name to Atochem North America, Inc.) submitted a petition proposing exemption from the requirement for a tolerance. It was denied by EPA in 1987. Over the next three years, the

registrant submitted waiver requests for a number of studies, a tolerance petition for residues of 1.5 ppm, and a proposal for a geographically restricted tolerance. All were denied by EPA. In 1991, the registrant committed to fill the outstanding data requirements. However, since some of the studies take years to complete, full Section 3 registration of cryolite for use on potatoes is still several years away.

In 1988, subsequent to the issuance of Section 18 Emergency Exemptions for use of cryolite to control CPB on potatoes in eleven states, EPA registered *two Bacillus thuringiensis* (Bt) products, M-One and Trident, for control of CPB. The Bt products suffer from lack of persistence conditioned by ultraviolet degradation and wash-off, but their primary limitation is the biologically narrow period of activity. If weather conditions are not conducive to application when CPB is in the susceptible stages to Bt (1 st and 2nd instar), then the critical window of opportunity has passed and efficacy is very low.

CHRONOLOGY OF IPM REQUIREMENTS FOR CRYOLITE USE UNDER SECTION 18s

1989 After the 1988 registration of two Bt products, the applicants for a Section 18 registration for cryolite on potatoes then had to convince EPA there was no "effective registered alternative" in order to meet the criteria for granting an emergency request. The applicants claimed that the Bt products could not substitute for cryolite because they have a narrow spectrum of activity against newly-hatched larvae, poor control of older larvae, fail to control adults, have short field persistence necessitating repeat applications, and growers lack experience using Bt.

EPA did not have sufficient data on file to conclude that Bt products would not provide an economically viable level of CPB control. However, CPB is a serious concern in potato production and, should Bt not perform satisfactorily, the growers would need a readily available alternative.

The 1989 Section 18 Emergency Exemptions were issued with the provision that cryolite be used in an IPM program which provided for the application of Bt prior to use of cryolite. The applicants were also instructed to develop data which indicated the economic level of control resulting from use of Bt in an IPM program with other registered products.

1990 Unusual rainfall in 1989 disrupted the first application of Bt, which is critical to keep the population in check. The Agency recognized that cryolite was an important tool in combatting CPB, yet wanted to increase grower familiarity with and use of Bt products. To this end, the Agency authorized -a maximum of two applications of cryolite, rather than the six requested. Applicants (which are states in this case) were also required to initiate a program designed to familiarize growers with the new Bt products and an IPM approach to controlling the pest. In order to support future requests for this use, applicants were again instructed to develop data demonstrating the economic level of control provided by use of Bt in an IPM program with other registered products.

Shortly after the 1990 authorizations, states asked for reconsideration of their request for six applications of cryolite. The applicants stated their interest in reducing reliance on a single control measure so as to retard the development of resistance, yet asserted that as many as 12 weekly applications of cryolite might be needed in areas with high populations of CPB. Therefore, they believed a limit of six applications provided considerable incentive for growers to adopt alternative methods.

The Agency amended and increased to six applications the Section 18 Emergency Exemptions granted to Pennsylvania, Rhode Island, New York, and New Jersey.

1991 After reviewing the 1991 requests -- including the states' discussion of their IPM programs and uses of the Bt products -- the Agency had continued concern that growers were reluctant to familiarize themselves with the new Bt products. Therefore, the Agency decided to require an even stronger incentive for its use. Applicants were allowed only two initial applications of cryolite. In order for EPA to consider authorizing additional applications, the applicant had to submit the following:

1. For each application of a pesticide to control CPB, provide: the date applied; the product applied; the application rate; acres treated; the cost of the chemical; the cost of labor to apply the chemical; the average daily temperature at the time of application; last date of rainfall; estimated date of next rainfall; last date of irrigation; percent of CPB population as adults, as 1st and 2nd instars, and as large instars.

2. A plan for an IPM program which provides a detailed description of how Bt products will be incorporated into the program, how monitoring pest populations will be conducted, and an estimate of the number of applications and quantity of cryolite to be used over the remainder of the season, and a commitment to collect the items listed under #1, above.

This chronology is based on a document prepared by Rebecca Cool, Section Head, Emergency Response and Minor Use Section, OPP/Registration Division, U.S. EPA.

Another clarification of policy in the guidance document that may result in a different implementation of state authority was in Section III, "Emergency Exemption for Pest Resistance Management." Here, EPA acknowledges that the development of resistance is a troublesome issue under Section 18. Since resistance occurs over a period of years, it is difficult to make a case that an emergency exists in any one year. However, the guidance document states:

> EPA's current position is that exemptions may be authorized for resistance management in cases where documented pest resistance to the registered alterna-

tive(s) has already developed and is expected to continue to result in significant economic losses.

In 199 1, 32 percent of the Section 18 applications granted by DPR had documented pest resistance as either the primary or secondary reason for the emergency status. In Florida, 61 percent of the Section 18s sought in 1990 and 1991 listed the emergence of resistance as the reason for the emergency status. Leafminer resistance -- especially in tomatoes, celery, and lettuce -- is particularly problematic for Florida growers and consumers nationwide. A working group comprised of growers, scientists, and representatives of Ciba Giegy Corporation and Merck & Co., Inc. was formed to develop and implement a leafminer resistance management program. This Committee has developed a series of guidelines for growers, monitored leafminer resistance in various populations, studied the genetics of resistance development in this pest, and supported an innovative Section 18 application to hasten the onset of further resistance development.

Florida had initially sought from EPA a joint Section 18 for the two products, explicitly requiring that only these two products be rotated, since these were the only two effective products remaining. The application cited Section IV of the guidance document, which states:

> There may be instances when the use of more than one pesticide is necessary and justifiable; such as when . . . there is a need to manage pest resistance or control different life stages of the pest.

Manufacturer and grower technical experts strongly felt that such a special Section 18 was needed to reduce the chances that resistance would emerge quickly, leaving growers with no alternatives. Technical justification was presented to Florida by the Committee and, by Florida, to EPA.

EPA refused to grant the joint Section 18 but did approve separate Emergency Exemptions for the two different products. The labels for these two products -- Agri-Mek 0.15 (avermectin) and Trigard 75W (cryomazine) -- were also amended to limit consecutive use of either to just two applications. Still, Florida officials and crop protection specialists feel EPA's action will reduce the chances that the two chemicals will be rotated as necessary to sustain efficacy.

Significant changes may also result from Section VII of the guidance document, "Emergency Exemptions for Safer Pesticides." This section states:

> EPA believes its regulations do not allow for the authorization of a Section 18 exemption based upon a determination that a pesticide which is unregistered for a particular use is safer than, or environmentally preferable to, a pesticide which is registered for that use.

This legal interpretation is causing problems in many states. For example, South Carolina has issued a Section 18 for a product on tomatoes for the last five years to prevent fish kills that had been documented in coastal counties where commercial tomatoes are produced. The product is as effective and economical as the registered alternative, and there have been no pesticide-related fish kills for five years. However, if EPA's "guidance" is taken literally, South Carolina will not be able to use its commitment to avoid fish kills as justification to seek a Section 18 Emergency Exemption next year.

In a letter from Clemson University, EPA's policy was strongly denounced. "For EPA to approve the use of Section 18s to alleviate potential crop. losses while prohibiting the same opportunity to alleviate a potential environmental loss is incomprehensible," said Von McCaskill, head of the Department of Fertilizer and Pesticide Control. However, McCaskill went on to offer EPA a way out of this interpretation:

> EPA requires that no equally effective registered pesticide be available before issuing a Section 18. This does not preclude an environmentally motivated petition if one considers that a pesticide which has an undesirable environmental effect is not as effective as a pesticide which has no such adverse effect.

SECTION 24(c): SPECIAL LOCAL NEED

Section 24(c) of FIFRA (40 CFR, Part 162) defines a *special local need* as "an existing or imminent pest problem within a State for which the state lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available." Under Section 24(c) of FIFRA, each state is authorized to register a new end-use product or an additional use of a federally registered pesticide product if *all* the following conditions exist:

1. There is a special local need for use within the State;
2. The use is covered by necessary tolerances, exemptions or other clearances if the use is a food or feed use;
3. Registration for the same use has not previously been denied, disapproved, suspended or cancelled by the Administrator, or voluntarily cancelled by the registrant; and
4. The registration is in accord with the purposes of FIFRA.

In California, DPR also requires efficacy data and a letter of authorization from the registrant allowing the state to register the product use specifically requested. According to one DPR Registration Specialist: "The letter is necessary to indemnify the state and to insure the manufacturer takes responsibility for all ramifications of use of the product. It really protects the grower, too." Lack of registrant permission is the most common reason DPR denies 24(c) applications. In 199 1, this accounted for 30 percent of the 24(c) applications DPR returned or denied.

A 24(c) Special Local Need (SLN) registration can be applied for by the manufacturer or basic registrant -- called a "first party SLN" -- or by anyone other than the registrant -- called a "third party SLN." A third party may be individual growers, grower associations, county agricultural commissioners, universities, or state or federal agencies (except EPA). Although third party registrations have long been allowed under FIFRA, many states are only now beginning to experiment with them. California has been a leader in issuing third party SLNs -- more than 1,000 have been issued since 1976. However, in the wake of the 1988 amendments to FIFRA requiring an annual maintenance fee for all registrations, many third parties can no longer afford to maintain these registrations. From 1985 to 1988, an average of 87 percent of 24(c) labels in California were held by third parties. From 1989 to 1992, the average declined to 47 percent.

There are three serious limitations that result from increased reliance on state registrations for pest control products. Section 18s are supposed to be issued for "urgent and non-routine" pest problems only. By definition, this would preclude issuance for more than a few consecutive years; yet, in 1990, EPA received and granted 29 use patterns which had been granted for four or more years. EPA could suddenly begin enforcing that policy, as, for example, recommended in a recent GAO report.

SLN 24(c) registrations are allowed on food crops only if a tolerance is in place, thus excluding access to new uses. Also, if a registrant abandons the registration, as many are in the wake of reregistration, then the tolerance will likely be lost as well, setting the stage for even fewer pest control tools for California growers.

By far the most serious implication of increased reliance on Section 18 and 24(c) registrations is that both have as a condition of issuance that there be no registered alternative. The use of only one tool to control a pest is a fundamental ingredient in the development of resistance.

Appendix 8

GLOSSARY

Allomones: Chemicals emitted by one species which modify the behavior of a different species, to the benefit of the emitting species.

Biochemicals: Chemicals that affect behavior, development and/or reproductive functions of pests. They fall into four general categories: semiochemicals, hormones, natural plant regulators, and enzymes.

Biointensive IPM: An IPM system which emphasizes dependence on three primary tactics: biological control, host plant resistance, and cultural management.

Biological controls [also biocontrol agents]: Naturally occurring organisms which exploit or otherwise help suppress pests. These organisms may be produced commercially for use in controlling pests or they may occur naturally in cropping systems. The classic definition of biological control encompasses parasitic and predatory insects, mites, nematodes, bacteria, fungi, and viruses. Some people favor a broader definition of biocontrol agents which includes naturally occurring compounds that help control or suppress pest populations.

Biorational pesticides: Typically naturally occurring biochemicals that may be extracted or synthetically produced; biocontrol agents. Biorationals may also be products of genetic engineering. They are often more "environmentally friendly" than conventional pesticides in that they are designed to be target-pest specific. This term is not formally incorporated in federal or state regulations. Other more specific terms -- such as biocontrol agent or semiochemical -- are preferred by regulators.

Cultural pest control: Generally physical or mechanical changes in an agricultural management system designed to help control pests by altering their habitat, available feed supply, or otherwise disrupt normal behavioral patterns. These may include clearing crop residue soon after harvest, crop rotations, clearing weeds from the field borders, changing water management practices, or altering the timing or method of planting.

Economic poisons: Regulatory term that defines the range of products that are subject to evaluation and registration in California by DPR before they can be used legally. The California Food and Agriculture Code defines an "economic poison" as any of the following:

(a) Any spray adjuvant.

(b) Any substance, or mixture of substances, which is intended to be used for defoliating plants, regulating plant growth, or for preventing, destroying, repelling, or mitigating any pest, as defined in Section 12754.5, which

may infest or be detrimental to vegetation, man, animals, or households, or be present in any agricultural or nonagricultural environment whatsoever.

Economic poisons include conventional agricultural pesticides which are typically petrochemically based and synthetically engineered and produced. Most pesticides used by farmers fall into three classes: herbicides that control weeds, insecticides that control insects, and fungicides for the control of plant diseases. Other classes of pesticides include soil and post-harvest fumigants which have broad ranges of biological activity, helping to control weeds, insects, nematodes, and plant diseases; nematicides are used to control nematodes; plant growth regulators are used to help time harvest operations, control fruit set, or speed maturity; and desiccants are used to defoliate plants to speed drying in the field so harvest operations can proceed.

Nonagricultural *economic poisons* include products used as wood preservers, as well as a host of products used in forestry; sterilants, sanitizers, and disinfectants; structural pest control products used to control termites, ants, and other insects that can invade or damage homes or other structures made of wood; products to control public nuisance pests such as mosquitos, ants, ticks, and fleas; and, chemicals used to control algae and weed growth in water, including swimming pools and water storage facilities.

Economic threshold: The pest population density or damage level at which a specific control measure should be taken to prevent economic injury from occurring. Economic threshold levels can change during a production season, reflecting temporal changes in a crop's sensitivity to damage from a pest species. Economic thresholds can also vary depending upon the combination of tactics and control practices a grower utilizes. In bio-intensive IPM systems, economic threshold levels are sometimes lower than in more traditional control programs, in an effort to suppress populations low enough so that nonchemical control measures will become effective for the remainder of the season, or during a period when key beneficial insects are particularly vulnerable.

Independent agricultural consultant: An individual who provides advice and recommendations to grower clients regarding the design and/or day-to-day management of agronomic and pest control systems, and who receives no direct payment or indirect financial gain from the sale or application of any product or input he or she recommends.

Integratedpest management ***[IPM]:*** A pest management system that anticipates and prevents pests from reaching damaging levels by using all suitable techniques, such as natural enemies, pest resistant plants, cultural management and judicious use of pesticides. [Source: National Coalition on Integrated Pest Management]

Kairomones: Chemicals emitted by one species which modify the behavior of a different species to the benefit of the receptor species.

Microbial pest control agents: Bacteria, fungi, viruses, and protozoans.

Minor use pesticide product: A product registered for a very narrow use. There are two basic ways in which a *minor* use product can be distinguished from other pesticide products: one is based on limited sales potential relative to the costs of compliance with regulatory requirements; the second is based on the extent of the acreage in need of treatment. The term *minor use* is defined as a crop grown on less than 300,000 acres, or a pest on a major crop that afflicts less than 300,000 acres nationwide in a legislative proposal advanced by the Minor Crop Farmer Alliance. In addition, *minor* use products are registered for a wide range of nonagricultural uses. Such products include specialty chemicals for sanitation, disinfection, weed control in nonagricultural settings, landscaping, home and garden uses, control of pests on pets, and other needs.

Opportunistic pest: A species either indigenous to the system, or which migrates into it, which: (1) fills an ecological niche left by a pest species controlled by a pesticide; and/or (2) thrives because its natural enemies were disrupted by pesticide use (classic definition of a ***secondary*** pest); and/or (3) was previously suppressed by a pesticide used to control another pest, dropped from the control system.

Pesticide resistance: The inherited ability in a strain of an organism to tolerate doses of toxicant that would prove lethal to a majority of individuals in a normal population of that species. This definition implies a statistically significant shift in LCx (or LDx) values that are normally established through laboratory bioassays. Laboratory documentation of resistance, however, does not necessarily indicate a current or impending loss of economic efficacy in the field. Resistance can be an advantage if it occurs in beneficial organisms that are natural enemies of the target pest.

Pheromones: Chemicals emitted by a species that cause behavioral changes in that same species.

Safe pesticide product: Absolute term ("absolute," in this case, meaning compared to a distinct standard, rather than in the sense of forevermore certainty) referring to a pesticide product with desirable physical, chemical, toxicological, biological, *and* ecological properties that render it capable of accomplishing its intended impact on target pest species while having insignificant or no adverse impact on humans, the environment, or the ecology of plant-pest interactions ("insignificant or no" meaning an exceptionally low probability of negative impacts: a finding that regulators would make based on available product and field use data).

If "safe pesticide products" were defined only by absolutes -- zero risk, no chance of posing risk -- then few if any products would fit within the definition.

Safer pesticide product: Relative term used to denote a pesticide product with one or more desirable physical, chemical, toxicological, biological, or ecological properties relative to other registered pesticide products or nonchemical pest control alternatives.

Safer pest control system: Relative term encompassing most integrated pest management and biocontrol systems, which -- relative to pesticide-intensive control systems -- successfully incorporate use of plant genetic, cultural, and biological control methods as a first line of defense.

Secondary pest: A species whose population is elevated above economic threshold levels by pesticide use intended to control another pest in the cropping system.

Semiochemicals: Chemicals emitted by plants or animals that bring about behavioral changes in living species. Semiochemicals do not cause developmental changes. They include pheromones, allomones, and kairomones.

Usepattern: The combination of how, where, how often, and under which restrictions and safety precautions a pesticide is approved for application on a given crop, on rangeland, in forests, or in non-agricultural settings, such as in homes or along rights-of-way, to control a particular set of target pests (for example, weeds, insects, and plant diseases).

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Independent program evaluations can be a traumatic and time-consuming experience for government agencies and the individuals who work in them. However, they can also initiate a forward-looking process of analysis and introspection, laying the foundation for constructive change. We hope this report lives up to that challenge.

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